

Exploring the Innovative Promise of Glycoscience

Seikagaku Corporation is a pharmaceutical manufacturer with a history of more than 70 years. As a pioneer in glycoscience, a research field with enormous hidden potential in drug discovery, we create innovative pharmaceuticals and medical devices.

Seikagaku contributes to the health, well-being, and improved quality of life for patients around the world in order to create a prosperous future.





Our Strengths

Source of Competitiveness

Seikagaku Corporation has developed a unique business model based on specialization in R&D and manufacturing. We contribute to medical care globally by developing and supplying high-quality pharmaceuticals and medical devices that leverage our unique technological capabilities.

Specialization in Glycoscience

Since its foundation, Seikagaku has focused its attention on the importance of glycoscience and has been working on applied research for new drug development. With our many research achievements, we are contributing to advances in medical science globally through our pioneering and specialized work in this niche field.

What is Glycoscience?

Glycoscience is a field of research into sugar chains and the complex carbohydrates, or glycoconjugates, that are formed through the binding of these sugar chains with other substances, such as proteins and lipids. Research in this field has demonstrated that sugar chains are deeply involved exchanges of information and substances among cells and are essential for various life phenomena, from the creation of life to aging.

There is also growing interest in the relevance of sugar chains to numerous diseases. Progress in the field of glycoscience is expected to lead to the development of new diagnostic methods and therapies.



2

State-of-the-Art Technology Related to GAG*

Through its many years of glycoscience research, Seikagaku has built up a library of GAG compounds and GAG-related enzymes, as well as a wide range of technologies based on the manipulation of these substances. We use these resources to develop new drugs. In its manufacturing operations, we apply our original GAG-related technologies and expertise to various processes, such as extraction, purification and culturing.

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

1 Creation of life through fertilization

Sugar chains are involved in the fertilization process that occurs when a sperm encounters an egg.

2 Determining blood type

The ABO blood type of a person is determined by the shape of sugar chains on the surface of their red blood cells

3 Water retention

Sugar chains, such as hyaluronic acid, protect cells against excessive water loss.

4 Cell growth control

gar chains control the activity of certain growth factors.

5 Protecting the body against external enemies

When a viral or other infection invasion occurs, sugar chains activate immune cells by stimulating macrophages, which are a type of white blood cell.

1 Viral and bacterial infection

Pathogens such as the influenza virus bind to specific sugar chains on a cell's surface before penetrating the cell itself.

2 Metastasis of cancer

When cells become cancerous, their sugar chains change shape and start to accelerate the proliferation and metastasis of cancer cells.

3 Diabetes

Abnormal sugar chain genes are believed to be one of the causes of this disease.

<Reference> It has been found that highly metastatic cancer cells feature an increased amount of giant sugar chains, which are much less prevalent in normal cells.



3

Unique Business Model Specialization in R&D and Manufacturing

Seikagaku does not have its own sales force. Instead, we offer our products through sales partners that have strengths in their respective product fields. This approach allows us to concentrate our management resources into R&D and manufacturing. This is evidenced by the fact that our R&D expenses account for 20% to 30% of net sales, and that 35%* of our employees are involved in R&D.

*Non-consolidated basis

Philosophy

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.

Inspiration Behind Our Motto

Creativity

Individual and corporate creativity are important for scientific advancement aimed at pursuit of truth. We can produce novel new products, new technologies, and new use of products by developing and applying unique and creative approaches, thus we can expect to achieve sound and stable corporate growth as a result of these efforts.

Fairness

We will adhere to principles of fairness that are recognized worldwide, and through self-discipline, will ensure we remain a company that is respected by society at large. Our "Creativity" and our "Dreams and Passion" must be built on a foundation of "Fairness."

Dreams and Passion

We have high ambition, and strive to achieve our dreams by working toward our ideals. This is the ultimate source of growth for our employees and our company.

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≪ Editorial Policy ≫

The Seikagaku Corporate Report 2023 is an integrated report containing both financial data and information about environmental, social and governance (ESG) initiatives. Non-financial information includes the history of our growth, our value creation processes, and initiatives in various business areas.

This report was created with the aim of providing stakeholders with a fuller understanding of our business activities and the value provided by Seikagaku Corporation.

<Target audience>

Seikagaku stakeholders, including shareholders and investors.

<Period covered by the report>

This report covers fiscal 2022 (April 1, 2022-March 31, 2023), but it also includes references to activities in fiscal 2023.

Our History

Success Based on Steady Pursuit of a Unique Vision

As indicated by the company name, Seikagaku Corporation focuses on research in the field of biochemistry (seikagaku in Japanese). The history of Seikagaku Corporation is a story of growth in step with the development and progress of glycoscience.

1950

Start of manufacture and sales of chondroitin sulfate for pharmaceutical products, following approval for pharmaceutical manufacturing in Japan



1960

Start of manufacture and sales of glucide-related research reagents developed in-house

*The research reagent business was terminated in 2012

1981

Start of manufacture and sales of world's first endotoxin colorimetry reagents

1987

Launch of ARTZ®* the world's first joint function improving agent with hyaluronic acid as its main active ingredient Launch of OPEGAN®



*The joint function improving agent ARTZ® delisted from the NHI drug price standard on March 31, 2022

1992

Launch of ARTZ®, a joint function improving agent, in Sweden under the name "Artzal®," making the start of full-scale overseas marketing of joint function improving agents

1993





ophthalmic viscoelastic device

2001

Launch of SUPARTZ®, a joint function improving agent, in the U.S. (now SUPARTZ FX®)



2007

Launch of MucoUp®, a submucosal injection agent for endoscopic surgery



2012

2016

Launch of Gel-One®, an intra-articular single-injection viscosupplement for the treatment of knee osteoarthritis, in the U.S.



Launch of SHELLGAN®, an ophthalmic viscoelastic device



2018

Launch of HERNICORE®. a treatment for lumbar disc herniation



2019



Launch of HyLink®, an intra-articular singleinjection viscosupplement for the treatment of knee osteoarthritis in Italy

2021

Launch of JOYCLU®, a joint function improving agent

1940s~

The world's first company to successfully produce

1947

Kosei Suisan K.K. (now Seikagaku Corporation) is established and opens the Kurihama Office (now Kurihama Plant) in Yokosuka City, Kanagawa Prefecture

1949

Masakane Mizutani (a former President of Seikagaku Corporation) commences trial production with the aim of realizing the world's first production of chondroitin sulfate on a commercial scale

1970s~

Pharmaceuticals using hyaluronic acid are developed.

1960

The Tokyo Research Institute (renamed the Tokyo Research Center in 1966) is opened in Shinjuku-ku, Tokyo

1962

The Company changes its name to Seikagaku Corporation

1968

The Tokyo Research Center (now the Central Research Laboratory) is relocated to Higashiyamato City, Tokyo

1975

The Takahagi Plant is opened in Takahagi City, Ibaraki Prefecture

1989

The Company's stock is registered on the Japan Securities Dealers Association market

1998

ISO 13485 certification is achieved

1997

Seikagaku Corporation acquires Associates of Cape Cod, Inc. (U.S.A.), a manufacturer and seller of endotoxin-detecting reagents, etc.



2004

Seikagaku Corporation is listed on the Second Section of the Tokyo Stock Exchange

2005

Seikagaku Corporation is promoted to the First Section of the Tokyo Stock Exchange

2013

The CMC Research Laboratory is established in Higashiyamato City, Tokyo (on the same site as the Central Research Laboratory)

Product diversification leveraging cutting-edge glycoscience technology. Toward a new stage.

2018~

2020

Seikagaku acquires CDMO3 business operator Dalton Chemical



Laboratories, Inc. (Canada) *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

2022

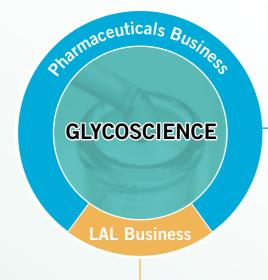
SEIKAGAKU NORTH AMERICA CORPORATION is established in Canada to manage pharmaceutical and medical device development in North America

Moved to the Tokyo Stock Market, Prime Market

05 SEIKAGAKU CORPORATION 2023

Business Activities and Products

Seikagaku has two business segments. In the Pharmaceuticals business, we offer a range of original products that leverage technologies and knowledge cultivated over many years as a glycoscience pioneer. In the LAL business, we offer endotoxin-detecting reagents and other products.



LAL Business

Seikagaku engages in the LAL business, manufacturing and selling endotoxindetecting reagents used in quality control of pharmaceutical and medical device manufacturing processes as well as a beta-glucan-detecting in vitro reagent for the diagnosis of deep fungal infections.

What are endotoxins?

Endotoxins are one of the major components of the outer membrane of gram-negative bacteria and exhibit strong pyrogenic activity even in minute amounts. Since serious side effects can be triggered by endotoxin contamination of injectable pharmaceuticals, biological products, or medical devices, they must be rigorously controlled, especially in directly administered injectable treatments.

What are glucans?

 $(1 \rightarrow 3)$ - β -D-glucans are structural components of the cell walls of fungi, as typified by molds and yeasts. Measurement of the glucan concentration in blood is widely used in auxiliary diagnosis of deep fungal infections and judgment of the therapeutic effect of antifungal agents.

Endotoxin-detecting reagents and devices

■ ENDOSPECY®, TOXICOLOR®, PYROCHROME®, etc.

Endotoxin-detecting reagents are reagents that measure endotoxins. Made from limulus amebocyte lysate (LAL), a substance extracted from the blood cells of horseshoe crabs, these reagents are used in quality control of injectable pharmaceuticals, biological products, and medical device manufacturing processes and water quality control of dialysate used in artificial dialysis.

■ PyroSmart NextGenTM

PyroSmart NextGen is an endotoxin-detecting reagent manufactured using genetic recombination technology without the use of blood harvested from horseshoe crabs. Seikagaku has successfully developed the world's first product consisting of recombinant proteins of Factor C, Factor B, and a coagulating enzyme precursor, which are components of horseshoe crab blood cells. Developed together with overseas subsidiary Associates of Cape Cod, Inc., PyroSmart NextGen was launched in Europe and the U.S. in April 2021 and introduced in Japan in May of the same year.

■ Endotoxin-detecting Systems

Seikagaku provides a wide range of endotoxin-detecting solutions to meet customers' needs, such as fully automatic and simultaneous multi-analyte measurement.

Beta-glucan-detecting in vitro reagent

■ Fungitell®

Fungitell is an in vitro diagnostic reagent used in the selection of treatment methods for deep fungal infections and judgment of therapeutic effect. Fungitell was developed by Seikagaku Corporation as the first product of its kind in the world and it is manufactured and sold in markets outside Japan by Associates of Cape Cod, Inc.





1000

ndotoxin-detecting reagents



Automatic endotoxin-detecting systems

Pharmaceuticals Business

The Pharmaceuticals business is Seikagaku Corporation's core business. Seikagaku manufactures and provides pharmaceuticals and medical devices made with GAG, as well as enzymes that act on GAG. GAG stands for glycosaminoglycans such as hyaluronic acid or chondroitin sulfate, the main ingredients in Seikagaku products. GAG is also a structural component of glycoconjugates. Seikagaku contributes to medical care in Japan and around the world by providing global-class high-quality products with its unique technologies.

Joint Function Improving Agents

■ ARTZ Dispo®, SUPARTZ FX®, VISCO-3®

ARTZ Dispo, a prefilled syringe product*1, is a multiple-injection version of ARTZ*2, a joint function improving agent containing hyaluronic acid as its main active pharmaceutical ingredient. When administered directly into the joint cavity, ARTZ Dispo is expected to reduce pain and inflammation. It has been approved and is supplied not only in Japan, but also in overseas markets, including the U.S., Asia, and Europe.

- *1 A kit with an injectable syringe that has to be filled with solution.
- *2 Delisted from the NHI drug price standard on March 31, 2022.

■ JOYCLU®

JOYCLU, a formulation in which hyaluronic acid and diclofenac (an anti-inflammatory drug) are chemically bound, is a joint function improving agent launched in May 2021. Improvement of symptoms of osteoarthritis of the knee joint and hip joint is expected from the administration of JOYCLU into the joint cavity once every four weeks. JOYCLU is the first joint function improvement agent in Japan indicated for the treatment of osteoarthritis of the hip joint.

■ Gel-One®, HyLink®

Originally developed for the U.S. market, Gel-One is an intra-articular single-injection viscosupplement for the treatment of knee osteoarthritis that contains cross-linked hyaluronate hydrogel as its main ingredient. Administration of only 3mL provides long-lasting benefits. HyLink, an intra-articular single-injection viscosupplement for the treatment of knee osteoarthritis that, like Gel-One, contains cross-linked hyaluronate hydrogel as its main ingredient, is currently sold in Italy and Taiwan.

Treatment for Lumbar Disc Herniation

■ HERNICORE®

HERNICORE, which contains an enzyme named "condoliase" as its active pharmaceutical ingredient, is Japan's first product for the treatment of lumbar disc herniation (intradiscal enzyme injection therapy). 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.

Ophthalmic Viscoelastic Devices (OVD)

■ OPEGAN®, SHELLGAN®, Sodium Hyaluronate 0.4 Ophthalmic Viscoelastic Preparation 1% SEIKAGAKU

The OPEGAN series of products allows the creation of appropriate intraocular space by viscoelastic properties of hyaluronic acid in cataract surgery. The product range includes seven types of different volumes and viscoelastic properties to meet specific treatment needs.

Submucosal Injection Agent for Endoscopic Surgery

■ MucoUp®

MucoUp is an endoscopic surgical aid that utilizes the excellent viscoelastic properties of hyaluronic acid. By injecting MucoUp into the submucosa beneath the lesion during the endoscopic resection of tumors in the gastrointestinal tract such as esophagus, stomach and large intestine, it creates a durable tissue uplift and provides improved procedural maneuverability and efficiency for ESD/EMR.

Bulk Products

■ Sodium hvaluronate, sodium chondroitin sulfate

Based on our unique extraction and purification technology, we manufacture and sell high-quality, high-purity hyaluronic acid and chondroitin sulfate, which are mainly raw materials for pharmaceuticals and cosmetics.

CDMO

■ CDMO services (contract development and manufacturing)

Seikagaku provides services to pharmaceutical companies, including manufacturing of chemical synthetics and pharmaceutical products on a contract basis and manufacturing process development. Seikagaku entered this business by acquiring Dalton Chemical Laboratories, Inc. as a subsidiary in March 2020.





SUPARTZ FX®



JOYCLU®



Gel-One®



HERNICORE®



OPEGAN® series





Bulk products

Message from the President & CEO



Strategic positioning of the mid-term management plan

Seikagaku continues to face an extremely adverse business environment due to factors including the progress of measures to control medical costs, notably drastic reform of the drug price system in Japan, and intensification of competition among pharmaceutical companies accompanying diversification of treatment options. In the area of research and development, the industry faces challenges including soaring costs and depletion of seeds for new drug development. Nevertheless, we are also seeing trends that propel new drug development, such as the emergence of regenerative medicine and other new therapeutic techniques and diversification of drug discovery modalities. We believe that a flexible response to these trends is necessary for Seikagaku to maintain a constant growth trajectory in this drastically changing business environment. Also, fulfillment of social responsibilities, starting with sustainability promotion, is increasingly important for the sustainable development of society and enhancement of corporate value. Responding to these

societal demands is an urgent priority for Seikagaku.

Accordingly, Seikagaku has instituted a mid-term management plan covering the four-year period beginning with the fiscal year ending March 31, 2023 (fiscal 2022). positioned as a period for achieving growth, and is implementing five key measures set out in the management plan: 1) Accelerate R&D utilizing unique drug-discovery technologies, 2) Maximize the product value of SI-6603 (treatment for lumbar disc herniation), 3) Maintain and enhance the business value of joint function improving agents, 4) Construct a global production system, and 5) Expand the LAL business through recombinant technologies. Building on a foundation solidified during the period of the previous management plan, we aim to achieve record-high business results in the final year of the plan by cultivating the ability to maintain a constant growth trajectory. Among the key measures, the market introduction of SI-6603 will be the focus of particular attention and effort.

Achievements versus mid-term management plan

Progress made in implementing the five key measures in the mid-term management plan is as follows.

1) Accelerate R&D utilizing unique drug-discovery technologies

New drug development is the source of growth for pharmaceutical companies. At Seikagaku, the aim of drug discovery is to create products that patients truly need, targeting glycosaminoglycans (GAG)* and GAG-related enzymes, substances that enable us to take maximum advantage of our original technologies and expertise.

Subject enrollment was completed in an additional Phase III clinical study in the U.S. evaluating SI-6603, a treatment for lumbar disk herniation that will provide a new therapeutic option for lumbar disk hernia patients in the U.S. In May 2023, we obtained topline results indicating statistically significant improvement in the primary endpoint of the study. Also, in a pivotal study in Japan of SI-449, an adhesion barrier that utilizes Seikagaku's own proprietary GAG cross-linking technology, in July 2023 we obtained topline results showing statistically significant adhesion prevention performance in both the primary endpoint and secondary endpoints of the study. We believe that SI-6603 is a new drug and SI-449 is a new medical device that meet unmet medical needs and will diligently proceed with preparations for an NDA submission to make possible delivery of products to patients at an early date.

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

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

SI-6603, the previously mentioned treatment for lumbar disk herniation, is a new drug we expect to become Seikagaku's largest growth driver for the future, and we consider obtaining regulatory approval and launching the product in the U.S. an important management priority. To promptly accomplish this, we are making full use of Canadian subsidiary Seikagaku North America Corporation, our North American development site, and proceeding on the basis of preparation of a comprehensive system to make possible smooth communication with the U.S. Food and Drug Administration (FDA) and ensure that the approval application and response to regulatory review are prompt and accurate.

Also, to maximize product value through early penetration at medical institutions, we are focusing on preparations for a product launch soon after approval is obtained in close collaboration with licensee Ferring Pharmaceuticals.

3) Maintain and enhance the business value of joint function improving agents

We consider it necessary to maintain and enhance the business potential of our mainstay joint function improving agents as core products that provide a solid foundation for the business. In Japan, we are expanding the production system and maintaining a stable supply as sales volume increases. Because these products are greatly affected by NHI drug price reductions, cost structure reform is essential. Various measures to achieve rapid cost reductions through changes in product material specifications are progressing.

Seikagaku also continues to gather and provide safety information on the joint function improving agent JOYCLU and is conducting clinical research to identify the cause of reported side effects.

4) Construct a global production system

At Dalton Chemical Laboratories, Inc., which became a Seikagaku subsidiary in March 2020, we are proceeding with a switch to in-house production of chemical synthetics and the partial transfer of manufacturing of pharmaceutical ingredients, and certain synergies are being achieved. We are also making headway with consideration of production system restructuring to make the Seikagaku Takahagi Plant and Dalton dual production sites by means such as the transfer of manufacturing of some products, including new products. We will continue making appropriate investments in pursuit of production optimization and efficiency from a global prospective.

5) Expand the LAL business through recombinant technologies

We have seen progress with an initiative to increase awareness of PyroSmart NextGen (a recombinant LAL reagent) by accumulating and publishing related scientific data. Also, we are working to increase the number of countries where Fungitell (a beta-glucan-detecting in vitro diagnostic test) is sold and to further expand into the hospital market.

In collaboration with U.S. subsidiary Associates of Cape Cod, Inc., we will continue our efforts to position Seikagaku as a leading company in the industry by creating unique products and services that competitors are unable to provide.

In fiscal 2022, implementation of the key measures in the management plan progressed largely as planned. We will continue to diligently implement the key measures in order to achieve our targets for the final year of the plan.

9 SEIKAGAKU CORPORATION 2023

Seikagaku also regards the pursuit of sustainability as an important priority, and we are devising and implementing effective measures that are based on the Basic Policy on Sustainability, instituted in 2021, and focused on six material issues, which give concrete shape to the policy. We are also expanding the scope of application of these measures to our subsidiaries.

In January 2023, Seikagaku established the Supply Chain Management Department with the aim of helping solve social problems by practicing sustainable raw procurement and providing a stable supply of products in cooperation with suppliers.

And, in March 2023, to further address environmental issues, we revised the CO₂ emission reduction target upward and began promoting new measures to achieve it.

Going forward, in addition to these measures, Seikagaku will promote initiatives to address

sustainability-related issues in areas including respect for human rights, consideration of the working environment for employees, fair and appropriate trading with business partners, and enhancement of corporate governance and will proactively disclose information to ensure sufficient communication with stakeholders.

Furthermore, Seikagaku considers the talents and skills of its employees to be an important corporate asset. As the importance of human capital further increases in the coming years, we will work to develop talented people capable of creating new value. And, to ensure that the contributions and successes of diverse employees are the driver of Seikagaku's sustained growth, we will proceed with preparation of an environment, systems, programs, and mechanisms to enable all employees to fully demonstrate their capabilities.

Seikagaku has identified and is focusing on six material issues related to the following eleven Sustainable Development Goals (SDGs). (For details, please refer to the section "Six Material Issues" beginning on Page 15.)





















To our shareholders and other stakeholders

It is Seikagaku's mission to contribute to the health and well-being of people around the world through the wider provision on a global scale of new pharmaceuticals that patients truly need. By fulfilling this mission, we aim to enhance our value to society as a pharmaceutical company.

As mentioned above, we are steadily implementing the key measures in the mid-term management plan, which has been newly formulated on the basis of a foundation solidified during the period of the previous management plan. The entire Seikagaku Group will work to achieve the targets set out in the plan.

We will also strive to strengthen corporate governance on the basis of high ethical standards by rigorously

practicing honest corporate activities and ensuring management transparency and will work to achieve the sustainable development of the Earth and society.

We request the continued understanding and support of our shareholders and other stakeholders.

President & CEO

Basic policy on profit distribution

Seikagaku believes that sustained profit growth and enhancement of corporate value contribute to the common interests of the shareholders. Management regards the return of profits to shareholders as an important priority and, while taking an annual dividend of ¥26 per share as the basis, will consider dividend increases, taking into account the trend in business performance, the financial position, and other factors. Also, while taking into consideration future business expansion and the total return ratio, Seikagaku will consider the purchase of treasury stock when appropriate. Seikagaku plans to pay an annual dividend of ¥26 per share, including the interim dividend, for the fiscal year ending March 31, 2024.

In addition, in order to solidify the business foundation and improve capital efficiency, the Company will make efficient and active business investments in R&D for creating new value, in production system development, and in sustainable activities and will flexibly make strategic investments offering prospects for future growth and synergy effects.



returns

- Shareholder Consider dividend increases, while taking an annual dividend of ¥26 per share as the basis, taking into account business performance and other factors.
 - · Consider the purchase of treasury stock when appropriate.

Business investments

- Continue efficient investments in R&D and production.
- · Make active business investments in sustainable activities.

Strategic

• Flexibly consider strategic investments with prospects for future growth and investments synergy effects.

	Forecast for Fiscal 2023	Fiscal 2022 Results
2nd Quarter	¥13.00	¥13.00
Fiscal Year-end	¥13.00	¥13.00
Annual Total Dividend	¥26.00	¥26.00
Dividend Payout Ratio	54.6%	64.2%

Value Creation

Innovating Novel Contributions and Approaches

As a company specializing in glycoscience, Seikagaku works to find solutions to social issues, increase its corporate value, and contribute to the health and well-being of humanity by creating novel and effective pharmaceuticals and medical devices and providing them to the world.

Social issues and the external environment

- Response to unmet
- Increased incidence of locomotive syndrome
- Super-aging society
- Increased healthcare access
- Declining probability of success in new drug development
- Protracted new drug development periods and soaring costs
- Contraction of the Japanese market, expansion of the global market
- Aggravation of environmental problems, environmental consideration (ESG), environmental



Forms of capital advantageous for R&D and domestic and international alliances

Financial capital

 A stable financial base that provides the source of funds for continuous new drug creation

Manufacturing capital

Manufacturing and quality management systems for the stable provision of high-quality pharmaceuticals

Intellectual capital

- Accumulated glycoscience-related chemical compound library
- Drug creation capabilities focused on target substances and high-priority target diseases

Human capital

People capable of creating new value by applying a high level of expertise in a challenge-driven corporate culture

Social capital

 Relationships of trust with stakeholders for realization of a sustainable society

Natural capital

- Low-environmentalimpact business activities as a life sciences company
- Corporate management that gives consideration to biodiversity

An original business model of specializing in R&D and manufacturing

Specialization in R&D and manufacturing



State-of-the-art technology related to GAG

- Advanced manufacturing basic technologies, including extraction, purification, cultivation, fermentation, and other technologies

 The ability to create diverse new pharmaceuticals based on the use of GAG and related enzymes

Business flow

R&D P23

Quality compliance

Material issues

- 1. Creation of truly useful pharmaceuticals and medical devices
- 2. Provision of a stable supply of pharmaceuticals and medical devices of guaranteed quality
- 3. Expansion of healthcare access and appropriate provision of high-quality medical information

Mid-term

management plan

Accelerate R&D utilizing unique drug-discovery technologies

П

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

Ш

Maintain and enhance the business value of joint function improving agents

Construct a global production system

V

Expand the LAL business through recombinant technologies

P17

Production

Marketing P31

P29

P15

4. Fair and ethical business activities and strengthening of corporate governance

- 5. Promotion of diversity and development of human resources
- 6. Engagement in environmetally-friendly corporate activities

Output

Provision of innovative, high-quality pharmaceuticals and medical devices, etc.

- Ethical pharmaceuticals, medical devices
- Bulk product
- CDMO services (contract development and manufacturing)
- LAL-related products

P07



Creation of economic value and social value

Medical institutions and patients

- Contribution to QOL improvement
- Creation of truly useful pharmaceuticals
- Provision of a stable supply of pharmaceuticals and other products of guaranteed quality

Shareholders

- Stable shareholder returns provided through sustained growth
- Fair information provision
- Enhancement of shareholder value

Employees

- Provision of growth opportunities
- Provision of an environment, systems, programs, and mechanisms to enable all employees to fully demonstrate their capabilities

Society

- Contribution to realization of a sustainable society
- Further development and refinement of glycoscience research technologies



Resolution of ocial issues and actualization of the management philosophy

> lycoscience for Human Well-being

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Six Material Issues

Seikagaku Corporation has identified six material issues on the basis of assessment of important issues that should be addressed on a priority basis in the interest of achieving sustainable development of society and enhancement of corporate value, in light of both their importance to the company and the expectations of society, including diverse stakeholders. By promoting initiatives related to these material issues, Seikagaku will contribute to achievement of the Sustainable Development Goals (SDGs) adopted by the United Nations.

Material Issue Identification Process

Step 1 Identification and organization of social issues

To identify material issues, we identified social issues based on factors including non-financial information disclosure guidelines; international frameworks, principles, and guidelines; and survey items from ESG assessment organizations. Furthermore, we closely examined issues specific to the pharmaceutical industry. On that basis, we compiled a list of 39 social issues.

Step 2 Prioritization of social issues

Using the list of 39 social issues identified in Step 1, we assessed the importance of issues to Seikagaku in light of its Corporate Philosophy, management strategies, and financial situation. Also, an external consultant scored, analyzed, and organized the issues from an outside perspective to assess the expectations of society, including diverse stakeholders. Based on the results of this assessment process, we prepared a social issues assessment matrix and shortlisted 17 high-priority social issues of importance to both Seikagaku and society.



Step 3 Identification of material issues through validation and grouping of issues

To validate the social issues assessment matrix prepared in Step 2, following discussion and careful examination of the matrix together with involved Seikagaku divisions and departments and an external consultant, the Board performed grouping of the 17 high-priority social issues and identified six material issues relevant to Seikagaku. The Board articulated reasons for selection and a future vision and determined objectives, initiatives, and monitoring indicators for each identified material issue and organized and confirmed their relevance to SDGs. The material issues were then deliberated and approved by the Board.

Material Issues

ivialeriai issues	rutule vision	Results (Fiscal 2022)		
Creation of truly useful pharmaceuticals and medical devices	Seikagaku increases its value to society by utilizing knowledge of glycoscience to continuously create pharmaceuticals and medical devices that are truly needed by society, and contribute to the health and well-being of people around the world. Seikagaku also considers intellectual property to be an important management resource and implements a global intellectual property strategy to contribute to the continuous creation of pharmaceuticals and medical devices. R&D P23	 SI-6603: Topline results indicating statistically significant improvement in the primary endpoint obtained in an additional Phase III clinical study in the U.S. (May 2023) SI-449: Results showing statistically significant improvement in both the primary endpoint and secondary endpoints obtained in a pivotal study being conducted in Japan (July 2023) SI-614: Follow-up observation completed in a Phase III clinical study in the U.S. (June 2023) Promoted creation of new research themes in disease areas with high unmet medical needs 		
Provision of a stable supply of pharmaceuticals and medical devices of guaranteed quality	Seikagaku strengthens its compliance and production systems to ensure uninterrupted access to reliable pharmaceuticals and medical devices for patients and medical institutions. Also, we manage risks associated with raw materials procurement and other business processes and take all possible measures to prevent risks from materializing. Quality compliance P29 Production P33	 Conducted 20 audits (paper and on-site) of contract manufacturers, suppliers, and distributors Confirmed GMP compliance and development of a quality culture through periodic management reviews Implemented measures to prevent reoccurrence of equipment problems and strengthened preventive maintenance 		



Material Issues	Future Vision	Results (Fiscal 2022)
Expansion of healthcare access and appropriate provision of high-quality medical information	Seikagaku promotes global distribution of pharmaceuticals and medical devices that address medical needs and, as a pharmaceutical manufacturer, strives to enhance information provision in order to achieve appropriate awareness of the safety and efficacy of our pharmaceuticals and medical devices and of diseases related to our products. Marketing P31	 Conducted a campaign to raise product awareness among patients in cooperation with a sales partner Conducted a total of five company-initiated clinical research and joint research projects and developed new evidence Gave two academic presentations and published three peer-reviewed papers for the purpose of enhancing product value Held seminars and briefings for medical practitioners in cooperation with sales partners and participated in exhibitions (total of 31 events) Published information on the Web for the purpose of providing information to physicians and increasing disease awareness among the general public
Fair and ethical business activities and strengthening of corporate governance	Seikagaku engages in business management to ensure that each employee not only complies with laws and regulations, but also behaves on the basis of high ethical standards. Seikagaku also continuously works to develop a highly effective corporate governance system. Corporate governance P43 Compliance and risk management P53	 Passed a Board of Directors resolution on TCFD disclosure and complied with the principles of the Corporate Governance Code Zero serious compliance-related incidents; conducted continuous training to foster compliance awareness Engaged in systems development, including revision of internal regulations, in connection with revision of the Whistleblower Protection Act Revised the Basic Policy on Internal Controls in accordance with changes in the external environment Enhanced explanations of important matters for outside directors in light of the results of Board of Directors effectiveness evaluation
Promotion of diversity and development of human resources 5 ***Exercises*** 10 ********************************	Seikagaku considers human resources to be an important corporate asset and works to develop people capable of creating new value. We develop an environment, systems, programs, and mechanisms to enable all employees to fully demonstrate their capabilities so that the contributions and successes of diverse employees are the driver of Seikagaku's sustained growth. Human Resources P41	 Disclosed human capital-related data, such as information on career training and employment diversity Introduced a new two-track HR system with the aim of organization building for maximization of resource value Began a review of the training curriculum for the purpose of developing autonomous employees Gathered and reflected in recruiting activities information on essential personnel in light of the medium-to-long-term and single-year business plans of each division and department (securing of diversity with regard to the proportion of mid-career recruits, gender classification, abilities, etc.)
Engagement in environmentally friendly corporate activities 13 ***********************************	As a member of society, Seikagaku aims to achieve balance between environmental protection measures and business growth and engages in business activities with low environmental impact in addition to obeying environment-related laws and regulations. Environmental impact reduction initiatives P36 Initiatives for biodiversity P39	 Achieved continuous reduction in energy use (five-year average energy consumption per unit of 96.7% / equivalent to Class S energy conservation performance*2) Achieved a reduction in CO₂ emissions (2.8% reduction year on year) Disclosed environmental data on the Web, including CO₂ emissions, waste and recycling volumes, and water pollution load Continued horseshoe crab release and conservation activities at an overseas subsidiary

- *1 Results for fiscal 2022 and beyond are partly included.
- *2 Business operators are classified according to their energy conservation results as Class S (superior energy conservation performance), Class A (average energy conservation performance), or Class B (energy conservation not progressing). Class S business operators are recognized on the Ministry of Economy, Trade, and Industry website as excellent business operators.

Mid-term Management Plan FY2022 to FY2025

Seikagaku has positioned the four-year period beginning with the fiscal year ended March 31, 2023 (fiscal 2022) as "A period for achieving growth" and formulated a new mid-term management plan. By implementing key measures set out in the plan on the basis of a profit foundation solidified during the period of the previous management plan, Seikagaku will aim to maintain a constant growth trajectory and achieve record-high business results in the final year of the plan.



Summary of Previous Mid-term Management Plan

Seikagaku was able to achieve positive results with respect to important measures set out in the management plan and solidified the foundation for returning to a growth trajectory by achieving the numerical targets in the plan.

- 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

- 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

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

Numerical Targets

	FY2021 results*1	FY2021 target	Percentage achievement
Net sales	¥31.2 billion	¥28.3 billion	+10.5%
Ordinary income	¥5.39 billion	¥4.5 billion	+19.9%
SKK EBITDA*2	¥5.54 billion	¥5.0 billion	+10.9%
Overseas sales ratio (excluding royalty income)	56.6%	50.0%	+6.6pt

^{*1} Converted to previous presentation categories

Overview of Key Measures

We expect the business environment to remain uncertain due to rapid changes in the pharmaceutical industry, such as National Health Insurance drug price reductions in Japan, healthcare system changes in overseas markets, the increasingly sophisticated demands of new drug development, rising development costs, and innovations in medical technologies. Also, fulfillment of social responsibilities, starting with sustainability promotion, is increasingly important for the sustainable development of society and enhancement of corporate value, and responding to this societal trend is a matter of urgent importance. (Information on sustainability initiatives is available in the section beginning on page 34.)

In this business environment, Seikagaku will implement the five key measures in the management plan to develop the ability to maintain a constant growth trajectory.

In addition, enhancement of employee engagement along with organizational strengthening and human resource development will be critical factors for carrying out the above five key measures. Seikagaku will work to solidify and improve the foundation for achieving sustained growth by stepping up investment to create an environment that promotes development and growth of human resources, the heart and soul of the Group's businesses.



Accelerate R&D utilizing unique drug-discovery technologies

P19



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

P20



Maintain and enhance the business value of joint function improving agents

Ш

IV

Construct a global production system

P21

V

Expand the LAL business through recombinant technologies

P21

Business foundation

Enhancement of employee engagement/
Organizational strengthening and human resource development

Numerical Targets

Seikagaku aims to achieve record-high business results in fiscal 2025, the final year of the management plan.

	FY2022 results	FY2025 target
Net sales	¥33.4 billion	¥40.0 billion
Operating income	¥2.1 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 business
- Ratio of R&D expenses to sales (excluding royalty income): target of 25%
- Exchange rate: ¥135/US\$1

17 SEIKAGAKU CORPORATION 2023

^{*2} SKK EBITDA: A profit indicator that adds depreciation to operating income

Summary of the Key Measures

Ι

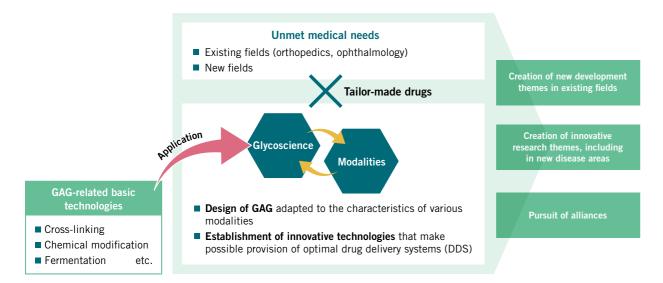
Accelerate R&D Utilizing Unique Drug-discovery Technologies

Create products that patients need utilizing Seikagaku's own GAG-related technologies and aim for steady advancement of the pipeline list.

Apply Seikagaku's own GAG*-related basic technologies to create new drugs that patients truly need, with an emphasis on unmet medical needs, by focusing on creation of new development themes in existing fields and creation of innovative research themes, including in new disease areas. Also, to increase the probability of success

of these efforts, pursue various alliances aimed at making early progress.

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



Pipeline List (Research and Development themes)

Advance existing pipelines with the aim of obtaining approval and introducing in the U.S. SI-6603 (a treatment for lumbar disc herniation), completing a Phase III clinical

study in the U.S. of SI-614 (a treatment for dry eye), and obtaining approval in Japan and initiating a clinical study in the U.S. of SI-449 (an adhesion barrier).

[Pharmaceuticals] (As of September 30, 2023)

Develop		Indication		Phase I	Phase II	Phase III	Application	Market approval
SI-6603	Condoliase	Lumbar Disk Herniation	USA			•		→
SI-614	Modified Hyaluronate	Dry eye	USA					
SI-613	Diclofenac etalhyaluronate sodium	Knee Osteoarthritis	USA					
SI-613-ETP Diclofenac etalhyaluronate sodium		Enthesopathy	Japan			ase I/II b scontinued (F	ebruary 2022))
SI-722	Steroid compound sodium chondroitin sulfate	Interstitial cystitis and bladder pain syndrome	USA	-	Phase I/II			

[Medical Devices]

Development code/Product name		Product name	Developed in	Pilot study	Pivotal study	Application	Market approval
SI-449	Cross-linked Chondroitin Sulfate	Adhesion Barrier	Japan		<		
SI-449	Cross-linked Chondroitin Sulfate	Adhesion Barrier	USA		-		

→ Planned progress as of the end of fiscal 2025

State of progress

- SI-449 (adhesion barrier): Results showing statistically significant improvement in both the primary endpoint and secondary endpoints obtained in a pivotal study being conducted in Japan (July 2023)
- SI-614 (treatment for dry eye): Follow-up observation completed in a Phase III clinical study in the U.S. (June 2023)

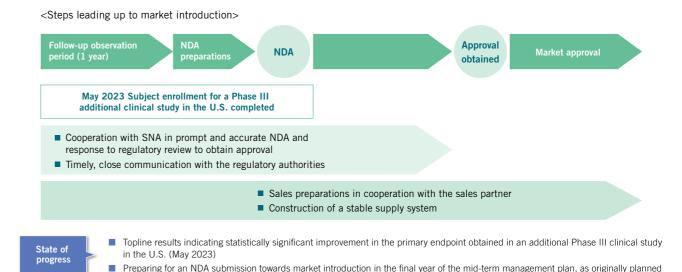
II

Maximize the Product Value of SI-6603 (treatment for lumbar disc herniation)

Aim for an NDA, approval, and market introduction during the period of the mid-term management plan.

Take maximum advantage of SEIKAGAKU NORTH AMERICA CORPORATION, established in Canada for the purpose of obtaining approval in the U.S. and launching SI-6603, a treatment for lumbar disc herniation, to ensure a prompt and accurate NDA and response to regulatory review. Also proceed with sales preparations and pursue

maximization of product value through early penetration at medical institutions in close cooperation with the sales partner. (For information on the development status and characteristics of SI-6603, please refer to the section "Research and Development" beginning on page 23.)



Ш

Maintain and Enhance the Business Value of Joint Function Improving Agents

Seek to enhance business value through maximization of Seikagaku products in the market for joint function improving agents and cost structure improvement.

Strive to maintain and enhance the business potential of the core products that support business management by increasing the presence of Seikagaku products in the mainstay domestic market for joint function improving agents. Since the domestic pharmaceuticals business is greatly affected by NHI drug price reductions, cost structure improvement is essential. Seikagaku will further

proceed with product material specification changes, which help ensure continuity of product supply, manufacturing process efficiency improvement, and other measures. Seikagaku will also continue gathering and providing safety information on the joint function improving agent JOYCLU with the aim of contributing to appropriate prescription on the basis of clinical research findings.

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



Maintenance and enhancement of business value that supports business management

State of progress

- Proceeding with production system expansion and a change of product materials for the purpose of further cost structure improvement due to a rapid market share increase for ARTZ
- Continued to gather and provide safety information on JOYCLU and conducted clinical research



Construct a Global Production System

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

Further reinforce a stable supply of products on the basis of an appropriate and efficient production system by



Seikagaku Corporation Takahagi Plant (Ibaraki Prefecture, Japan)

▶ Please refer to "Overview of Production Sites" on page 33.

making Dalton Chemical Laboratories, Inc. and the Seikagaku Takahagi Plant dual production bases.



DALTON CHEMICAL LABORATORIES, INC. (Toronto, Canada)

▶ Please refer to "Overseas Subsidiaries" on page 60.

Endotoxin-detecting reagent PyroSmart NextGen®

State of progress

Proceeding with construction of a manufacturing system at Dalton to create dual formulation sites, in Japan and overseas



Expand the LAL Business Through Recombinant Technologies

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

Further reinforce a stable supply of products on the basis of an appropriate and efficient production system by making Dalton Chemical Laboratories, Inc. (Toronto, Canada) and the Seikagaku Takahagi Plant (Ibaraki Prefecture, Japan) dual production bases, including transfer of production of some products.

▶ Please refer to "Overseas Subsidiaries" on page 60.



- 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

For details on the mid-term management plan:

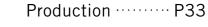
https://www.seikagaku.co.jp/en/ir/management/midtermplan.html

Business Progress

Research and Development ······· P23

Quality Compliance ····· P29

Marketing ····· P31









Research and Development

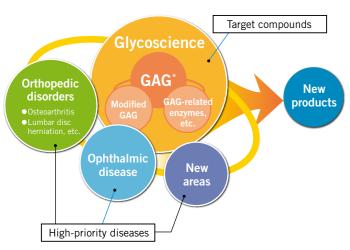
Seikagaku engages in research and development of innovative drugs in our specialty field of glycoscience. And we contribute to the health and well-being of people around the world.



R&D policy

In order to rapidly and continuously create new products, Seikagaku engages in efficient R&D activities by focusing on target compounds and prioritizing target diseases. The focus of our drug discovery is glycosaminoglycans (GAG), which are the structural components known as glycoconjugates.

In research spanning nearly 70 years, we have accumulated a wealth of experience and expertise related to GAG drug discovery research and GAG production and formulation technologies. Today, we apply hyaluronic acid or unmodified GAG in pharmaceuticals and also engage in research and development of modified GAG produced using a cross-linking technology as well as enzymes and other substances that act on GAG. Given the properties of GAG, we focus mainly on orthopedic disorders and ophthalmic diseases as high-priority areas for now, where we have expertise through the development of such products as ARTZ Dispo joint function improving agent and OPEGAN ophthalmic viscoelastic device.



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

Direction of R&D and future drug discovery approach

Seikagaku possesses a GAG compound library, GAG-related enzymes, and wide-ranging technologies for manipulating these substances. We actively utilize these assets, accumulated in the course of research spanning many years, in drug discovery activities. We have also developed a global network of collaborating glycoscience researchers and engage in multiple joint research projects with universities and research institutes.

Specifically, we continue to focus on drug discovery for orthopedic disorders and ophthalmic diseases and have also begun utilizing GAG-related technology to expand new fields. At the same time, we make efforts to maximize the value of our products on the market or themes in development through expansion of indications, additional formulations, changes in dosage and administration, etc.

Until now, Seikagaku has followed a drug discovery approach of increasing the bioactivity of GAG, mainly through GAG modification and processing, and we are currently applying GAG to drug delivery systems (DDSs). Furthermore, going forward, we will also adopt an approach focused on the biological functions of sugar chains to open up new possibilities in drug discovery.

In our DDS, we are researching technologies that utilize the characteristics of modified GAG to freely control drug dose and the location and timing of release. We will pursue drug discovery and development capable of responding to a wide range of unmet medical needs by designing GAG for various modalities—not only low-molecular compounds, but also so-called middle molecules, such as peptides and nucleic acids, and high polymers, such as proteins—and providing Seikagaku's own DDS.

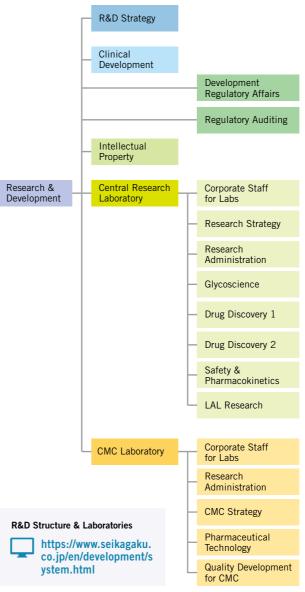
Research and development organization

To ensure close coordination of the drug development process from its upstream to downstream, Seikagaku has put in place an organizational structure in which the departments involved in R&D are consolidated under the control of the Research & Development Division. This integrated organization covers every R&D activity from clinical development to new drug application (NDA) and intellectual property strategy. In this structure, the Central Research Laboratory is in charge of exploring candidate

substances and evaluating efficacy, safety, and pharmacokinetics, and the CMC Laboratory is responsible for production of investigational drugs, design of manufacturing processes, and consideration of commercial production.

[Research & Development Division Structure]

(As of July 1, 2023)



Drug discovery research

The Central Research Laboratory, Seikagaku's drug discovery research center, cultivates the creativity of researchers in a fulfilling research environment, equipped with advanced facilities, and places importance on fostering a self-help culture.

Seikagaku contributes unique knowledge, technology, and expertise related to glycoscience to benefit drug discovery research, and actively collaborates with universities and companies in Japan and overseas to accelerate the search for ideas and development of new technologies. Through these efforts, we work to create original pharmaceuticals and medical devices on the basis of specialized technologies and creative ideas.

[Overview of Research Units]

Glycoscience: Exploration of GAG (glycosaminoglycans) and related compounds as pharmaceutical candidate substances

Drug Discovery: Synthesis of new candidate substances with GAG as the basis for research, evaluation of their efficacy and function, and research on their actions and mechanisms

Safety & Pharmacokinetics: Evaluation of pharmacokinetics and toxicity profiles of candidate substances in vivo

LAL Research: Development of manufacturing technologies for reagents and diagnostics based on exploratory research of new technologies

CMC research

The CMC Laboratory produces investigational drugs, designs manufacturing processes, engages in quality development, and examines commercial production of products under development created by the Central Research Laboratory. By engaging in development from the R&D stage in collaboration with the Production Division, the CMC Laboratory aims to ensure the stable supply of high-quality pharmaceuticals and medical devices that comply with regulations in Japan, the United States, and Europe and to increase the speed of new drug development under a system integrated from research to production.

[Overview of Research Units]

Pharmaceutical Technology: Design of active pharmaceutical ingredients, pharmaceutical formulations, packaging, and manufacturing processes for candidate substances and consideration of commercial production

Quality Development for CMC: Research of physicochemical properties, development of testing methods for quality evaluation, and quality assurance of investigational drugs

Research and Development

Development Pipeline

[Pharmaceuticals] Development code/Product name Indication Developed in Phase II SI-6603 Condoliase Lumbar Disk Herniation USA SI-614 USA Modified Hyaluronate Diclofenac etalhyaluronate sodium Knee Osteoarthritis USA Phase IIb (Discontinued (February 2022)) SI-613-ETP Diclofenac etalhyaluronate sodium Japan Enthesopathy Interstitial cystitis and USA Phase I/II sodium chondroitin sulfate bladder pain syndrome

[Medical Devices]

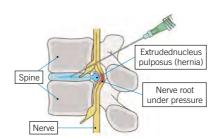
	Development code/Product name	Indication	Developed in	Pilot study	Pivotal study	Application	Market approval
SI-449	Cross-linked Chondroitin Sulfate	Adhesion Barrier	Japan				

SI-6603 (treatment for lumbar disc herniation)

SI-6603, which contains condoliase as its active pharmaceutical ingredient, is a treatment for lumbar disc herniation directly injected into the intervertebral disc. It has the special characteristic of not requiring general anesthesia and being less invasive to patients than surgical treatment. Since a single injection is expected to improve the symptoms of lumbar disc herniation by reducing intervertebral disc pressure and relieving pressure on the nerve root, SI-6603 can contribute to improving patients' quality of life as a new treatment option.

patients' quality of life as a new treatment option.

In Japan, marketing approval was obtained from the Ministry of Health, Labour and Welfare in March 2018, and SI-6603 was launched on August 1, 2018 as HERNICORE 1.25 units for intradiscal injection.



Administration of SI-6603

Follow-up observation in an additional Phase III clinical study being conducted in the U.S. was completed in March 2023, and topline results showing statistically significant improvement in the primary endpoint of the study were obtained in May. Seikagaku will now proceed with preparations for an NDA.

SI-613 (treatment for osteoarthritis)/SI-613-ETP (treatment for enthesopathy)

SI-613 is a formulation in which hyaluronic acid and diclofenac (an anti-inflammatory drug) are chemically bound using a drug binding technology proprietary to Seikagaku. By releasing diclofenac through hydrolysis, relief for osteoarthritis and enthesopathy can be expected.

In Japan, marketing approval was obtained for SI-613 for its efficacy and effect on osteoarthritis (knee joint and hip joint) on March 23, 2021, and it was launched as joint function improvement agent JOYCLU® 30mg Intra-articular Injection in May of the same year. It is the first joint function improving agent in Japan indicated for osteoarthritis.



Administration of SI-613

Since shock or anaphylaxis has occurred in Japan, to promote appropriate use, Seikagaku conducted clinical research to identify the cause of the side effects.

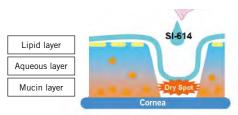
Seikagaku will analyze data obtained through this research and continuously consider proposals that will lead to correct use.

The primary efficacy endpoint in a late-stage Phase II clinical trial in Japan of SI-613-ETP for the treatment enthesopathy was not met, and the Company will prioritize identification of the cause of shock or anaphylaxis. For these reasons, development of SI-613-ETP was discontinued in February 2022.

SI-614 (treatment for dry eye)

SI-614, an ophthalmic solution, is a modified hyaluronate produced using Seikagaku's proprietary technology. Instilling this solution as an eyewash is expected to improve dry eye symptoms by stabilizing the tear film and promoting corneal wound healing.

Follow-up observation was completed in a Phase III clinical study in the U.S. with the objective of evaluating efficacy and safety in June 2023, and Seikagaku is currently analyzing the data obtained from the study.



Administration of SI-614

SI-722 (treatment for interstitial cystitis and bladder pain syndrome)

SI-722 is a novel chemical compound in which a steroid is conjugated with chondroitin sulfate using Seikagaku's proprietary glycosaminoglycan modification technology and drug delivery systems. SI-722 injected into the bladder is thought to demonstrate an improvement effect in symptoms such as of frequent urination and bladder pain, by releasing a steroid with an anti-inflammatory effect.

While a Phase I/II clinical trial in the U.S. experienced delays in the trial schedule due to the spread of COVID-19, subject enrollment was completed in January 2021, and tolerability in the patients of this trial has been confirmed. Currently, we are exploring the next phase of trials based on the data we have obtained.



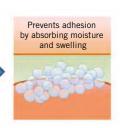
Using sustained release of steroids to provide long-lasting improvement

Administration of SI-722

SI-449 (adhesion barrier)

SI-449 is a powdered adhesion barrier whose main ingredient is cross-linked chondroitin sulfate developed using Seikagaku's own glycosaminoglycan cross-linking technology. SI-449, which has the property of absorbing moisture and swelling, is expected to prevent or mitigate post-operative adhesion formation by forming a barrier between the surgical wound site and surrounding tissues after application. Development of this subject is progressing with an eye not only on domestic development, but also globally.





Use of SI-449

Follow-up observation in a pivotal study in Japan was completed in June 2023, and topline results showing statistically significant improvement in the primary endpoint and secondary endpoints of the study were obtained in July. In light of the results, together with the outcome of a pilot study in the field of gynecology, Seikagaku will proceed with preparations for an NDA at an early date.

Research and Development

The clinical study process and paths of new drug development

To create new drugs, it is necessary to conduct various studies to evaluate efficacy and safety. Clinical studies are conducted to confirm whether drug candidates are actually beneficial to humans, following completion of research processes such as basic research and non-clinical studies.

Clinical studies are ordinarily divided into three phases and conducted at medical institutions such as hospitals in conformance with rigorous standards after the consent of subjects (healthy persons or patients) has been obtained.

A Phase I clinical study, the initial phase, is ordinarily conducted for the main purpose of examining the pharmacokinetics (absorption, distribution, metabolism,

and excretion) and safety (adverse events and side effects) of investigational drugs in a small number of healthy subjects. A Phase II clinical study examines efficacy, safety, and pharmacokinetics and confirms optimal dosage and usage in a small number of patients. A Phase III clinical study, the final phase, objectively verifies efficacy and safety in comparison to existing approved drugs or placebos in large numbers of patients.

Ordinarily, more than ten years is required from discovery of a candidate substance until its approval as a new drug. Within the long, difficult new drug development process, clinical development is considered to hold the key to whether an NDA can be filed.

[The Drug Research and Development Process]



TODICS

The TATENO Forum contributes to enhancement of R&D capabilities

Each year, the Central Research Laboratory holds the internal TATENO Forum to share research results relating to new ideas and technology creation. In addition to young and mid-career researchers, employees from other business sites participate in discussing the future potential and contribution to medical needs of each research theme. In 2023, the forum was mainly on-site for the first time in three years, with presentations and open discussions on a total of 41 topics. Participants expressed enthusiastic comments such as, "Holding the forum on-site after a hiatus allowed for active discussion" and "I was exposed to wide-ranging views through cross-sectional discussion. I want to apply the insights I obtained in creating development themes."

By deepening interaction among employees through the exchange of ideas and information sharing and contributing to enhancement of

Seikagaku's R&D and technological capabilities, the Central Research Laboratory will continue its efforts to originate and create development themes, such as new pharmaceuticals that people truly need.

*The forum name was taken from the location of the Central Research Laboratory (Tateno, Higashiyamato City, Tokyo).



Presentation given by a researcher



Explanations of research results stimulate the exchange of ideas

Seikagaku and glycoscience

Seikagaku's Management Creed states: "We create safe and useful products for human well-being with basic research based on glycoscience." In keeping with this creed, we have made glycoscience the core foundation of our business and explicitly adopted a stance of respect for learning. Seikagaku's origin is closely bound up with this creed.

In 1950, Seikagaku became the first company in the world to successfully produce chondroitin sulfate, which is a sort of GAG, on a commercial scale. This breakthrough laid the foundation for our current business, which is centered on glycoscience. The manufacture of chondroitin sulfate marked the starting point for expansion of our business to bulk products, as well as reagents and diagnostics, and this has led to the strengthening of our ties to glycoscience-related academia and research institutes.

Through this close relationship with academia, we acquired the idea of applying hyaluronic acid in pharmaceuticals. R&D activities spanning many years culminated with the successful development and launch of ARTZ, the world's first joint function improving agent whose main ingredient is hyaluronic acid. The development of HERNICORE, a treatment for lumbar disc herniation that contains condoliase, an enzyme that degrades GAG, also originated from collaboration with academia.

Seikagaku will continue to make Glycoscience the central focus of R&D activities and, on the basis of research results in the field of glycoscience achieved in collaboration with universities and research institutes, strive to create pharmaceuticals and medical devices and deliver them to patients around the world.

The difficulty of applying glycoconjugates to pharmaceuticals

GAG are formed when amino sugars (sugars that include nitrogen atoms) and uronic acids (a class of sugar acids) or galactose are linked together to form chain-like structures (sugar chains). Sugar chains are known in the life sciences as the third biological chain, along with nucleic acids and proteins, but they have complex chemical structures because they are molecules that handle various kinds of information within living organisms. In research in areas such as structural analysis, automatic synthesis, and large-scale synthesis, this complexity poses characteristic difficulties not found

in other biological materials.

However, long-term efforts in the industry and academia have advanced the structural analysis and synthesizing technologies of sugar chains. In addition, the genes of sugar-chain synthesizing enzymes and degrading enzymes have been comprehensively identified, and our understanding of the homeostasis of sugar chains in living organisms and their pathological function is advancing. This progress in glycoscience technologies is closely linked with Seikagaku's drug discovery research.

Intellectual property strategy

Appropriate protection of intellectual property relating to Seikagaku's technologies, products, and other assets is essential not only for maintaining corporate competitiveness, but also for continuing to create and supply unique, high-quality pharmaceuticals and medical devices. Seikagaku views intellectual property as an important management resource and engages in global intellectual property-related activities.

The Intellectual Property Department engages in activities related to acquisition of intellectual property rights (patents, designs, trademarks, copyright, know-how, etc.) and their protection. It works closely with the Research & Development Division involved in drug discovery as well as with Business Development & Marketing Division, Production Division, and other relevant Company organizations.

Fair R&D activities

In the interest of conducting fair R&D activities, Seikagaku has established the Ethical Review Committee for Research Using Human Specimens and the Animal Experimentation Ethics Committee. Through comprehensive examination of the appropriateness of clinical studies and research using human specimens and animal experimentation in these committees, including ethical and scientific perspectives, Seikagaku strives to rigorously ensure ethical consideration in R&D activities.

Ethical considerations concerning research using human biological materials

https://www.seikagaku.co.jp/ja/development/research/research01.html (Japanese only)

Ethical considerations in non-clinical studies

https://www.seikagaku.co.jp/ja/development/ research/research02.html (Japanese only)

Quality Compliance

Seikagaku's mission is to provide patients with a continuous supply of safe, beneficial, high-quality pharmaceuticals and medical devices. We have constructed corporate quality assurance and compliance systems in accordance with laws, regulations, and standards.



Quality compliance system

Seikagaku places quality first, from R&D to post-marketing, by complying with overseas pharmaceutical laws and regulations, including GxP* regulations and guidelines. In Japan, as a marketing authorization holder, Seikagaku operates a legal compliance system under the officer responsible for pharmaceutical matters (Responsible Officer) in accordance with the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices ("PMD Act"). And, the general marketing compliance officer, quality assurance supervisor, and safety management supervisor oversee appropriate quality management and pharmacovigilance operations. To reliably provide pharmaceuticals and medical devices to patients around the world, we will continue to operate in accordance with global standards.

* GxP stands for Good XXX Practice, a collective term for standards established to ensure the efficacy, safety, and quality of pharmaceuticals and medical devices from R&D to post-marketing.

Quality management system based on global standards

To provide a stable supply of high-quality pharmaceuticals and medical devices, in accordance with our Quality Policy, we have developed a world-class quality management system. At the development stage, we ensure reliability under Good Laboratory Practice (GLP) and Good Clinical Practice (GCP) standards. To ensure compliance with laws and regulations and maintenance of quality assurance systems through the post-marketing stage, each year we systematically conduct self-inspections and internal audits to confirm the status of operation of the quality management system and promptly take corrective and preventive actions as necessary.

Seikagaku has obtained ISO 13485 certification for the development, manufacture, and distribution of sodium hyaluronate-based viscoelastic products for the treatment of osteoarthritis of the knee and periarthritis of the shoulder. We strictly maintain and control quality at all stages from product design and development to post-marketing in conformance with these manufacturing control and quality assurance systems.

ISO 13485 is an international standard for quality management systems established by the International Organization for Standardization (ISO) that prescribes

requirements concerning the design, development, and manufacturing of medical devices. In Japan, ISO 13485 has been adopted as an ordinance on standards for manufacturing control and quality control of medical devices and in vitro diagnostics.

[Laws and Regulations Governing Pharmaceuticals and Medical Devices

	1 -	·· > 2 ··	3	4	-> 5
Life cycle	Basic research	Development	NDA	Manufacturing, quality control, information provision, and product supply	Post- marketing
Pharmaceuticals Medical Laws and Regulations	• PMD Act • GLP	• PMD Act • GLP • GCP • GMP for investigational products	• PMD Act	• PMD Act • GMP • GQP	• PMD Act • GPSP • GVP
Medical devices egulations	• PMD Act • GLP	• PMD Act • GLP • GCP • QMS	• PMD Act	• PMD Act • QMS	• PMD Act • GPSP • GVP

- PMD (Pharmaceuticals and Medical Devices) Act Act on securing quality, efficacy and safety of products including pharmaceuticals and medical devices
- GLP: Good Laboratory Practice
- Standards for conducting non-clinical studies on safety
- GCP: Good Clinical Practice
- Standards for conducting clinical studies
- GMP: Good Manufacturing Practice
- Standards for manufacturing control and quality control in manufacturing
- GVP: Good Vigilance Practice
- Standards for post-marketing safety management of drugs, quasi-drugs, cosmetics and medical devices and regenerative medicine products
- GQP: Good Quality Practice
- Standards for quality control of products GPSP: Good Post-marketing Study Practice
- Standards for conducting post-marketing surveys and studies on drugs
- QMS: Quality Management System
- Ordinance on standards for manufacturing control and quality control of medical devices and in vitro diagnostic reagents

Safety management

Sometimes side effects not observed in the development stage come to light after the launch of a new pharmaceutical product. In accordance with Good Vigilance Practice (GVP) standards, Seikagaku conducts post-marketing pharmacovigilance activities involving promptly and appropriately collecting, evaluating, and sharing feedback information on the side effects of pharmaceuticals prescribed at medical facilities. Through these activities, we prevent the expansion of side effects and promote safety assurance and appropriate use of new drugs.





Executive Vice President Toshiyuki Okada

Although Seikagaku Corporation sells pharmaceuticals, medical devices, bulk products (hereafter collectively "products"), and measurement equipment and provides services in Japan and overseas, the company believes that its greatest responsibility as a manufacturer is to continuously provide patients and medical practitioners with products of the same standard of quality as approved by the regulatory authorities. Specifically, this means observing product-related laws and regulations, manufacturing products that conform to standards using approved manufacturing methods, assuring efficacy and safety, and providing to medical practitioners without omission product information required by law, such as usage methods necessary for correct use, storage methods,

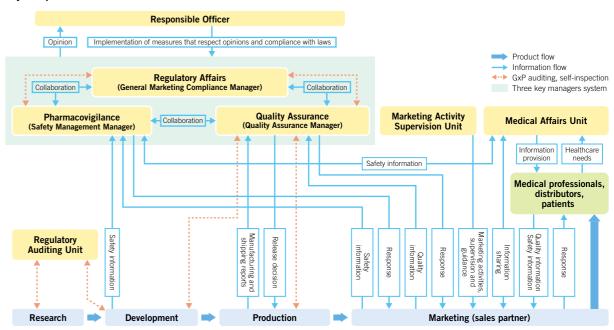
expiration dates, and serial numbers.

It is also important to take measures to minimize risks by investigating whether safety risks are occurring either with respect to products themselves or to patients after use of products and by providing timely and appropriate information to medical institutions. At Seikagaku, this is the true function of Reliability Assurance, which is responsible for the serious business of protecting the safety and health of patients in our role as a pharmaceutical and medical device manufacturer.

The overseas sales ratio of Seikagaku products is increasing each year, and in 2024 we plan to submit an application for manufacturing and marketing approval in the U.S. for a treatment for lumbar disk herniation. This will mark the first time for Seikagaku to sell a biological preparation overseas, and we are undertaking to understand and comply with various new laws and regulations in order to establish a global reliability assurance system and carefully proceeding with preparation of new drug efficacy and safety information in close collaboration with the local sales partner.

Reliability Assurance aims to establish a system that will enable us to continue to reliably fulfill our responsibilities as a manufacturer of pharmaceuticals and medical devices and will strive to maintain and improve product safety and reliability so that as many patients and medical practitioners as possible are able to correctly use products of the same high quality, wherever in the world they may be.

[Quality Compliance Structure]



Medical information collection and provision activities

Laws and regulations, as well as self-regulation by industry associations, are becoming increasingly rigorous as compliance awareness in society grows. Seikagaku has established the Marketing Activity Supervision Unit to provide correct, scientifically accurate information related to product safety and efficacy. This unit ensures compliance with regulations by examining presentation materials, etc., and monitoring information provision activities.

Also, Seikagaku has established the Medical Affairs Unit to provide current scientific knowledge to external professionals independently from the marketing division. Scientific experts apply an ethical perspective, which aids medical progress by creating and disseminating medical evidence relating to disease information and products within Seikagaku's focus, such as orthopedic disorders and ophthalmic diseases.

Materiality 3

Marketing

Seikagaku has a business model of supplying products through external partnerships in Japan and overseas in collaboration with pharmaceuticals and medical device sales companies. In this way, it intends to focus and develop its business activities without having an in-house pharmaceuticals sales division.



Pharmaceuticals and medical devices

To efficiently deliver these products to patients globally, Seikagaku forms partnerships with pharmaceutical companies that have expertise in each market, including Japan, rather than selling directly to pharmaceutical wholesalers and medical institutions. Through their activities, our partners, in conformance with laws and regulations on pharmaceutical sales, provide appropriate information on product efficacy, safety, quality, and other matters to physicians on a timely basis.

Seikagaku, in close cooperation with sales partners, formulates sales strategies, supports preparation of product information materials, analyzes the market environment, including information on competing products, and collaborates with academic societies. Through these activities, we support sales partner activities and appropriately promote market penetration for our products.

As part of product life cycle management, Seikagaku is implementing product modifications that respond to needs of a changing market. One example is the conversion of the material for syringes, used for the joint function improving agent ARTZ Dispo, from glass to plastic. Through these efforts, we are adding value to our products.

Furthermore, we have been accelerating overseas business expansion in recent years. We are working to increase sales in countries where we already do business, and to meet global medical needs, we are implementing a plan to introduce existing products and products in development into new markets.

Bulk products

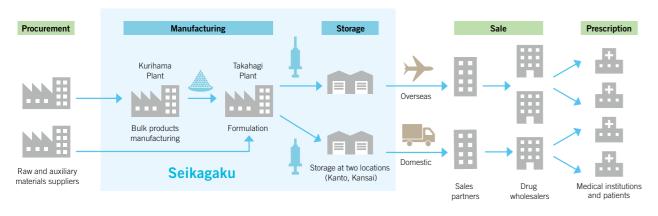
Using proprietary extraction and purification technologies, Seikagaku manufactures high-purity and high-quality hyaluronic acid and chondroitin sulfate and sells them to pharmaceutical and cosmetic companies, and others globally

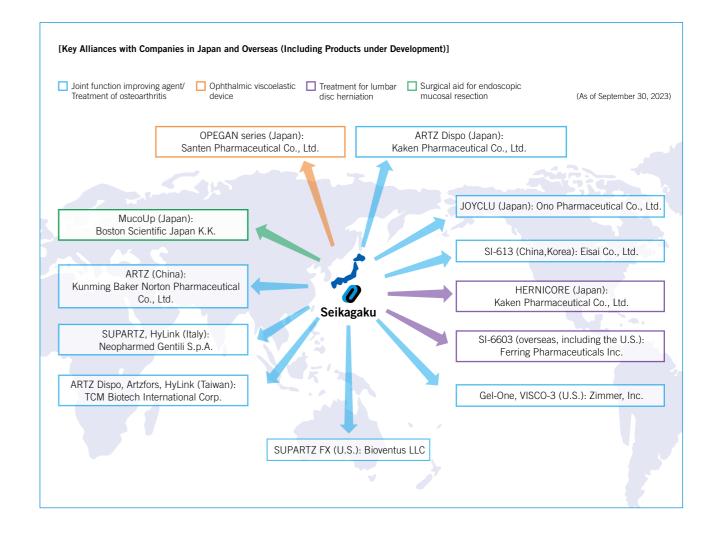
The bulk products are widely applied as active pharmaceutical ingredients for orthopedics and ophthalmology. In recent years, those bulk products are also being considered as new application materials in the regenerative medicine area.

Contract development and manufacturing organization (CDMO)

A contract development and manufacturing organization (CDMO) is 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. In March 2020, we added to our business by acquiring Dalton Chemical Laboratories, Inc. as a subsidiary.

[Supply Chain for Main Products]





LAL business

Seikagaku is engaged in the development of the LAL business in Japan, which is mainly used in quality control of injectable pharmaceuticals and medical device manufacturing processes and water quality control of dialysate used in artificial dialysis.

Wholly owned subsidiary Associates of Cape Cod, Inc. (ACC) handles overseas business development. ACC is the first company in the world to successfully develop endotoxin-detecting reagents from limulus amebocyte lysate (LAL), and it obtained U.S. Food and Drug Administration (FDA) approval in 1977. ACC plays an important role in the overseas business expansion through

its global sales network, mainly in the U.S. and Europe, through the manufacturing and sales of endotoxin-detecting reagents, as well as beta-glucan-detecting in vitro reagent to diagnose invasive fungal disease.

Furthermore, Seikagaku has successfully developed the world's first product consisting of recombinant proteins of Factor C, Factor B, and a coagulating enzyme precursor, which are components of horseshoe crab blood cells. We launched gene-recombinant endotoxin-detecting reagent PyroSmart NextGen through ACC and in Japan in 2021.

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Foundation for Value Creation

Data Section

Production

Seikagaku steadily manufactures high-quality products at its two pharmaceutical manufacturing plants in Japan and endotoxin-detecting reagent manufacturing plant in the U.S. and plant related to CDMO business in Canada.



Production structure compliant with global standards

Companies that manufacture pharmaceuticals and medical devices must comply with the current regional regulations and engage in stable, continuous manufacturing. In order to deliver high-quality products to patients, Seikagaku complies with Good Manufacturing Practice (GMP) in Japan, the U.S., and Europe and strives for ever more rigorous manufacturing processes. Also, in the area of manufacturing control and quality control, we use computer systems to improve the completeness of records and work to improve production efficiency through rigorous regular checks, elimination of human error, and improvement of manufacturing processes. We will continue to pursue continuous improvement so as to manufacture and supply high-quality products that comply with global standards.

Ensuring a stable supply of products

It is important for pharmaceutical companies to provide stable supplies. Seikagaku prepares for major disasters and other risks by diversifying raw materials and maintaining appropriate inventory levels. At the Takahagi Plant, responsible for manufacturing the finished products, we have introduced a quake-absorbing structure that helps isolate the main production buildings from earthquakes. Through these measures, we now have a system capable of stable, reliable product production even in an emergency.

Furthermore, to cope with product supply risk from disruption of distribution in a disaster, we maintain a certain level of product inventory and have pharmaceutical warehouses in two separate locations: at the Takahagi Plant in Ibaraki Prefecture near Tokyo and in Hirakata City, near Osaka.

[Overview of Production Sites]

Takahagi Plant (Takahagi City, Ibaraki Prefecture)

The Takahagi Plant is responsible for manufacturing finished pharmaceuticals and medical devices, including the joint function improvement agents that are Seikagaku's mainstay products. Today, the Takahagi Plant occupies a site of approximately 86,000 square meters and has five production buildings and some 200 employees. The Takahagi Plant is one of the world's largest manufacturing sites for hyaluronic acid pre-filled syringe formulations*. Sterility assurance is strictly required for the manufacture of injectable formulations, and the plant has minimized the risk of contamination by implementing unattended, automated manufacturing processes. The plant possesses facilities and equipment that can be adapted to optimal sterilization methods suited to the product characteristics.

*A kit with an injectable syringe that has been filled with solution.



Kurihama Plant (Yokosuka City, Kanagawa Prefecture)

The Kurihama Plant, which manufactures bulk products, has some 100 employees and manufactures high-purity hyaluronic acid and chondroitin sulfate for use mainly as active pharmaceutical ingredients.

The most important characteristic of the Kurihama Plant is that it specializes in the manufacturing of bulk products by extraction and fermentation. The plant applies advanced chondroitin sulfate extraction and fermentation technologies nurtured over many years since the founding of Seikagaku and has expertise in the efficient manufacture of high-purity bulk products from chicken combs, the raw material of hyaluronic acid, and shark cartilage, the raw material of chondroitin sulfate.

The Kurihama Plant is also responsible for the manufacturing processes for condoliase, the active pharmaceutical ingredient of HERNICORE, a treatment for lumbar disc herniation.



Information on U.S.-based Associates of Cape Cod, Inc. and Canada based Dalton Chemical Laboratories, Inc. is provided in the section "Overseas Subsidiaries" on page 60.

Sustainability Progress



Sustainability Management

Basic Policy on Sustainability

Seikagaku Corporation Group, guided by the core values expressed in the motto Creativity, Fairness, Dreams and Passion, aims to sustainably develop together with society by living up to its management creed: "Under the principle of respect for learning, we contribute to human well-being by creating and supplying the world with safe and useful pharmaceutical products based on glycoscience."

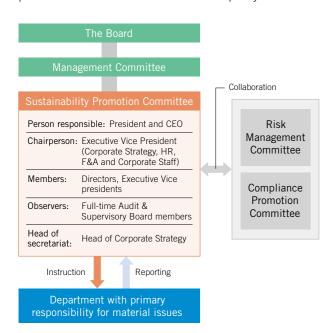
In undertaking this, we meet the expectations of our diverse stakeholders and practice behaviors aimed at creating fair and honest relationships on the basis of high

corporate ethical standards that reflect profound awareness of our social mission and responsibilities as a life sciences company.

On the basis of these ideals, Seikagaku Corporation Group seeks to grow as a corporate group that is valued by the world by providing a stable supply of truly useful, high-quality products created from innovative R&D activities and will contribute to the health and well-being of people around the world by working toward the sustainable development of the Earth and society.

Sustainability Promotion Structure

Seikagaku has designated the president and CEO as the person responsible for promotion of sustainability-related activities and established the Sustainability Promotion Committee, which is chaired by the executive vice president. The committee discusses the policy on



1) Board of Directors

The Board decides, gives instructions, and supervises important matters relating to basic management policies, the mid-term management plan, the business plan, etc.

2) Management Committee

The Committee discusses and decides important matters relating to corporate management, such as the conclusion of important contracts, establishment of company rules and regulations, and formulation and modification of business execution plans.

3) Sustainability Promotion Committee

The Committee formulates basic policies and promotion measures relating to sustainability promotion, examines and assesses progress, and provides guidance and education. As a rule, the Committee meets twice yearly, and agenda items and deliberation results are reported or submitted for consideration by the Board of Directors and Management Committee as the chairperson considers necessary.

sustainability-related activities, promotion measures, and other sustainability-related matters and verifies and assesses progress toward objectives. Important matters are reported on and considered at meetings of the Board following deliberation by the Management Committee.

Fiscal 2022 Results

materiality.html

- Application of sustainability-related policies to major overseas subsidiaries https://www.seikagaku.co.jp/en/sustainability/ our_policy.html
- Information gathering and progress management related to material issues https://www.seikagaku.co.jp/en/sustainability/
- Disclosure of ESG-related data https://www.seikagaku.co.jp/en/sustainability/esgdata.html
- Analysis of climate change-related risks and opportunities https://www.seikagaku.co.jp/en/sustainability/tcfd.html
- \bullet Setting of CO₂ emissions reduction target for 2030 aligned with the government target and formulation of reduction measures
- Formulation and implementation of an education and training plan for Seikagaku officers and employees
- Awarded a Silver sustainability rating for 2022 by EcoVadis*

Future Initiatives

- Implementation of CO₂ emissions reduction measures (facilities replacement and updating, procurement of renewable energy, etc.)
- Establishment of a supply chain risk assessment process
- Enhancement of communication with business partners
- Cultivation and development of human resources capable of creating new value
- Creation of an environment and development of systems, programs, and mechanisms to enable all employees to fully demonstrate their capabilities

*EcoVadis is a company that operates a platform for assessing the sustainability supply chains of more than 100,000 businesses in 175 countries worldwide using original assessment criteria related to four sustainability themes: Environment, Labor & Human Rights, Ethics, and Sustainable Procurement.





Basic Policy on Sustainability

Seikagaku Corporation recognizes that the global warming problem is a critical challenge facing the world and considers contributing to the realization of a sustainable society an important mission for companies. As a pharmaceutical company and as a member of society, Seikagaku Corporation aims to achieve balance between environmental measures and the company's growth and will implement initiatives to achieve business activities with low impact on the environment.



[Environmental Policy]
https://www.seikagaku.co.ip/en/sustainability/policy.htm

CO₂ emissions reduction initiatives

Keenly aware of the importance of protecting the global environment and the responsibilities associated with manufacturing activities, Seikagaku observes environment-related laws and regulations and voluntarily engages in environmentally friendly business activities. We aim to balance environmental measures and business growth by continuing the energy-saving activities implemented heretofore and strengthening initiatives for efficient utilization of water resources, waste reduction and recycling, and other environmental improvements.

We have established the Energy Conservation Promotion Committee with the objective of promoting energy conservation activities and reducing CO₂ emissions and are managing energy use, implementing improvement measures for achieving energy use reduction targets established at each business site, and conducting energy conservation-related education and training. Furthermore, we have put in place a structure for increasing groupwide efficiency in which the

Committee coordinates energy use and CO₂ emissions volume and reduction measures each fiscal year, reports to the Management Committee, and discusses these matters. At the Takahagi Plant, which uses the most energy, we have increased thermal efficiency and reduced CO₂ emissions by updating boilers to convert boiler fuel from heavy fuel oil A to liquid natural gas (LNG). Furthermore, we have reduced energy use through initiatives such as conversion to LED lighting fixtures at production sites and laboratories and repairing and reinforcing steam pipes and steam traps. By continuously engaging in such energy conservation activities, we have achieved our average energy reduction rate targets for the five-year period up to fiscal 2022.

Also, to ascertain CO₂ emissions in the supply chain, we have estimated* and posted Scope 3 emissions on our website. We intend to refine the estimate and gradually reduce emissions, prioritizing the largest sources.

*Estimated using a simple calculation method

TOPICS

Surviving the "decisive decade" — Efforts to reduce environmental impacts

In the Glasgow Climate Pact, an outcome of the 26th session of the Conference of the Parties to the United Nations Framework Convention on Climate Change (COP26), held in 2021, a target of limiting atmospheric temperature increase to 1.5°C above pre-industrial levels was set. The ten-year period until 2030 has been called the "decisive decade" for climate action. To do its part in achieving Seikagaku's fiscal 2030 CO₂ emissions target (page 38), on October 3, 2022 the Takahagi Plant launched the 2030 Promotion Committee to boost collaboration with involved departments and steadily implement reduction measures.



The Committee formulates and implements plans through close cooperation among its four teams. These teams cooperate through periodic team activities and monthly team leader meetings and are responsible for formulating concrete environmental impact reduction measures and conducting education and training at the Takahagi Plant. In fiscal 2022, the Energy Team promoted CO₂ emissions reduction by soliciting proposals and formulating details of medium-term reduction activities. The Process Improvement and Materials Team reduced work process times, mainly through process improvements. The Industrial Waste and Environment Team bolstered recycling by reviewing waste sorting methods at the time of disposal. The Awareness Team raised employee awareness through SDGs study groups, hanging posters promoting waste sorting, and other means.

Environment

Information Disclosure Based on the TCFD Recommendations

Seikagaku Corporation considers addressing climate change to be an important management priority and is implementing measures to combat climate change. Since June 2022, Seikagaku has disclosed the status of its response to the TCFD*1 recommendations and to climate-related risks and opportunities.

In The Task Force on Climate-related Financial Disclosures (TCFD) was established by the Financial Stability Board (FSB) in December 2015 at the request of the G20 Finance Ministers and Central Bank Governors Meeting to examine climate-related information disclosure and the response of financial institutions to climate change. In its final report, published on June 2017, the TCFD recommended disclosure by companies and other organizations of information on climate change risks and opportunities in the areas of governance, strategy, risk management, and metrics and targets.

Governance

In accordance with the Basic Policy on Sustainability, Seikagaku Corporation has identified by a resolution of the Board of Directors important issues that should be addressed on a priority basis (materiality) in the interest of achieving sustainable growth for Seikagaku and realizing a sustainable society.

We established the Sustainability Promotion Committee for the main purpose of addressing sustainability-related issues. In principle, the Committee meets twice a fiscal year to discuss the action policy for climate change issues, promotion measures, and related matters and to examine and assess progress. Also, climate change risks and opportunities are included among the group-wide risks evaluated by the Risk Management Committee, discussed by the Sustainability Promotion Committee, and reported to the Board of Directors, and the Board monitors and oversees progress in addressing these risks. The president and CEO serves as the officer responsible for the Sustainability Promotion Committee and Risk Management Committee.

Strategy

To conduct a climate-related risk and opportunity materiality assessment, we used the following scheme to identify and assess scenarios for three categories: transition risks, physical risks, and opportunities. In addition to the Net Zero Emissions by 2050 Scenario*2 (NZE) proposed by the Intergovernmental Panel on Climate Change (IPCC) and the International Energy Agency (IEA), which assumes a temperature rise of 1.5°C, and the IEA's Stated Policies Scenario (STEPS), which

assumes a 4°C rise, we carefully examined internal and external information and assessed the potential effects of climate-related risks and opportunities on businesses, strategy, and financial planning.

*2 Seikagaku analyzes risks and opportunities based on the following scenarios: Net Zero Emissions by 2050 Scenario (NZE): 1.5°C rise Stated Policies Scenario (STEPS): 4°C rise

Scenario Analysis Scheme



Risk Management

In risk management, each division and department implements initiatives in response to risks and opportunities in accordance with the Corporate Risk Management Regulations. The Sustainability Promotion Committee, established in December 2021, and the Risk

Management Committee share information on climate change risks, integrate and manage these risks as a form of business risk, and periodically report important risks to the Board of Directors.

Risk and Opportunity Analysis Based on Medium- and Long-term Scenarios

Transition risk

Risks and Opportunities	Details	Scale of Financial Impacts 1.5°C / 4°C	Time Frame	Response and Resilience
Policy and legal risk	Rising costs due to tightening of regulations, such as introduction of a carbon tax	Medium / Medium	Medium to long term	Mitigation of carbon tax burden through promotion of energy conservation and introduction and expanded use of renewable energy; cost reductions from initiatives such as reduction of raw materials use
Market risk	Rising costs due to introduction of eco-friendly raw materials, etc.	Medium / Medium	Medium to long term	Mitigation of carbon tax burden through promotion of energy conservation and introduction and expanded use of renewable energy; cost reductions from initiatives such as reduction of raw materials use
Reputation risk	Investor resistance or decline in personnel recruitment opportunities due to inadequate sustainability information disclosure, etc.	Medium / Small	Short to medium term	Pursuit of corporate value enhancement and greater opportunities to secure investment and personnel through proactive sustainability information disclosure

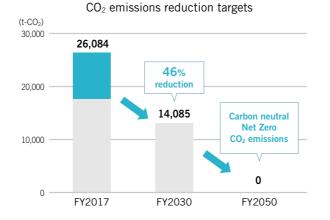
Physical risk

Risks and Opportunities	Details	Scale of Financial Impacts 1.5°C / 4°C	Time Frame	Response and Resilience
Acute	Risk of damage to production facilities, etc. resulting from increasingly serious extreme weather events; rising costs of restoration and prevention measures; temporary shutdowns due to supply chain disruption	Medium / Large	Medium to long term	Damage minimization through a continuous review of the business continuity plan (BCP), upgrading of BCP measures and strengthening of impact assessment and response capabilities along supply chains
Chronic	Declining outpatient numbers due to a healthcare crunch accompanying climate change-related spread of infectious disease	Medium / Medium Long		Promotion of R&D of long-acting drugs that entail little outpatient burden
Chronic	Decrease in natural resources used as raw materials or quality deterioration due to the impact of climate change on ecosystems	Small / Medium	Medium to long term	Promotion of research on substitute raw materials and transition from biological raw materials to recombinant raw materials, such as fermented materials

Opportunities

Risks and Opportunities	Details	Scale of Financial Impacts 1.5°C / 4°C	Time Frame	Response and Resilience
Energy and resource efficiency	Production facilities efficiency improvement	Small / Small	Medium to long term	Cost reductions from promotion of energy conservation and introduction and expanded use of renewable energy
Products, services, and markets	Climate-change related spread of infectious disease	Medium / Medium	Long term	Promotion of R&D in the infectious disease diagnosis field, etc.

Metrics and Targets



CO₂ emissions reduction targets (Scope 1 & 2: non-consolidated)

- 46% reduction by 2030 (compared to fiscal 2017)
- Pursuit of carbon neutrality by 2050
- Scope 3 calculation (disclose by 2025)

Effective measures to consider in the medium to long term

- Thorough energy conservation actions and educational activities
- Installation of high-efficiency equipment and solar power generation facilities
- Procurement of carbon-free energy and credits



Initiatives for Biodiversity

Recognizing the importance of biodiversity in business as a life sciences company, Seikagaku Corporation strives for biodiversity preservation and the



[Biodiversity Policy] https://www.seikagaku.co.jp/en/sustainability/biodiversity.html

Horseshoe Crab Conservation Activities of Associates of Cape Cod, Inc.

Since Seikagaku's U.S. subsidiary Associates of Cape Cod, Inc. (ACC) manufactures and sells reagents using a substance extracted from horseshoe crab blood cells as a raw material, it continuously engages in horseshoe crab conservation activities to protect this precious natural resource. In addition to supporting the American horseshoe crab, in 2019, ACC began providing assistance for activities to maintain the population of Asian horseshoe crabs in the form of customized aquaculture equipment and training. Maintaining the population involves growing survivable juveniles produced by in vitro fertilization of sperm and eggs and releasing them into the natural environment. ACC has long engaged in this activity and accumulated related technology and expertise.

This assistance will be made available to academic institutions and private sector researchers around the world. Organizations receiving assistance are granted a license to use intellectual property relating to horseshoe crabs owned by ACC free of charge and are also provided with instructions regarding in vitro fertilization methods and training in the operation of highly efficient aquaculture equipment. The number of American horseshoe crabs that ACC has released in the Commonwealth of Massachusetts had reached about 1.25 million as of December 31, 2023.

In parallel with these conservation activities, ACC has also focused on development of gene-recombinant endotoxin-detecting reagents that can be manufactured without using blood harvested from horseshoe crabs.

PyroSmart NextGen, launched by ACC for sale in overseas markets in April 2021 and launched by Seikagaku for sale in Japan in May, was commercialized by ACC based on the results of R&D conducted for many years at Seikagaku.

Since PyroSmart NextGen follows the same cascade pathway as naturally sourced products, the same test methods and instrumentation can be used when the product is substituted for traditional naturally sourced reagents. ACC seeks to contribute to sustained environmental conservation by providing the option of choosing a gene-recombinant reagent in addition to taking measures to maintain the population of horseshoe crabs.

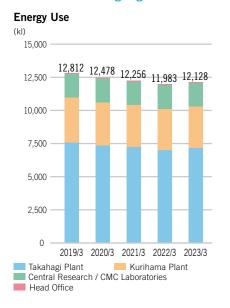
The Seikagaku Group will continue to actively support

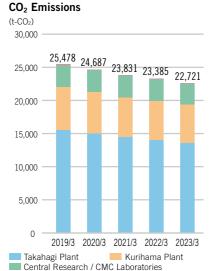
activities to conserve horseshoe crab populations and strive to use this resource in a sustainable manner.

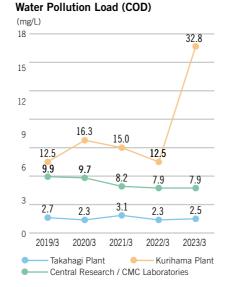


Horseshoe crab juveniles

Environmental Highlights







Social Contribution Activities

problems in pursuit of harmony and continuous growth together with local communities. And we pursue respect for learning by engaging in global research assistance and sponsoring activities that support the development of

Glycoforum, a website for comprehensive information on glycoscience research

Since 1997, Seikagaku has operated Glycoforum, an academic website specialized in glycoscience research that shares information about research findings to contribute to the development of glycoscience, which is one of Seikagaku's areas of specialization.

As a portal site for glycoscience information, the website disseminates in a timely manner scientific papers from researchers active on the cutting-edge of the field, explanations of technical terms, and academic conference information. The site enjoys strong support from researchers in Japan and overseas.

Support for the Mizutani Foundation for Glycoscience

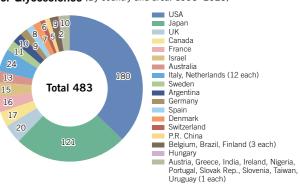
The Mizutani Foundation for Glycoscience, a public interest incorporated foundation, was established in 1992 with an endowment from the late Masakane Mizutani, former president of Seikagaku Corporation, for the purpose of contributing to the welfare of humanity through the advancement and development of glycoscience. The foundation provides research grants to glycoscience researchers in Japan and overseas and supports conferences. In fiscal 2022, the foundation provided research grants totaling ¥70.41 million to 15 grant recipients. Seikagaku endorses the purpose of the Foundation and has continuously supported its activities since its founding.

https://www.glycoforum.gr.jp/index.html



https://www.mizutanifdn.or.jp/index.html

Number of Grant Recipients by the Mizutani Foundation for Glycoscience (By country and area: 1993-2023)



Helping patients obtain early treatment

- Knee osteoarthritis Hiza Ikiiki (Sprightly Knees), a website for provision of information concerning knee osteoarthritis to the general public Knee osteoarthritis is a disorder by which the knee joint is strained due to aging, excessive exercise, or weight increase and the cartilage gradually wears away. Hiza Ikiiki explains basic knowledge concerning knee osteoarthritis and diagnosis and treatment methods in an easy to understand way.
- Koshi-hernia.jp, a website for the provision of information concerning lumbar disc herniation to the general public

Koshi-hernia.jp explains basic knowledge concerning lumbar disc herniation and its symptoms in an easy to understand way. It also provides information on changes in symptoms according to the season or weather, the impact of the disorder on work and lifestyles, and other information obtained from the findings of online patient surveys.

Through these websites, Seikagaku will provide correct knowledge and information to enable as many patients as possible to obtain early, correct treatment.





https://koshi-hernia.jp/ (Japanese only)





Promotion of Diversity and Development of Human Resources

Seikagaku Corporation recognizes that respecting human rights through busine s is important for remaining a company that contributes to healthy and lives for people around the world, and also creates a prosperous future and respecting human rights in accordance with the UN Guiding on Business and Human Rights, we hereby initiate the Seikagaku Corporation Human Rights Policy (the "Policy").



Human Rights Policy] https://www.seikagaku.co.jp/en/sustainability/our_policy/humanright.html

Development of human resources

Seikagaku Corporation considers human resources to be an important corporate asset and works to cultivate human resources capable of creating new value. To ensure that the contributions and successes of diverse employees are the driver of Seikagaku's sustained growth, we will proceed with creation of an environment and preparation of systems, programs, and mechanisms to enable all employees to fully demonstrate their capabilities.

Seikagaku also strives to provide fields for each person to grow and thrive in. We endeavor to cultivate autonomous employees who go about their work with enthusiasm and pride and produce results. We promote upskilling and career development through a combination of systematic education in various training programs, workplace education through day-to-day work, and job rotation.

The curriculum for systematic education is depicted in the diagram below. We conduct a variety of training programs for everyone from young employees to executives with the objective of promoting the growth of individual employees and the Company.

Work-life balance

To help its employees achieve a good work-life balance, Seikagaku has introduced flextime at all business sites, including laboratories and plants, and established a weekly "no overtime day." To help employees balance their personal lives with their work, Seikagaku encourages them to develop their own work styles. For example, we now have a reduced-working-hours system for employees who provide childcare and nursing care, and employees may also accumulate lapsed annual paid leave for use during prolonged illnesses or to cope with extended childcare and nursing care needs.

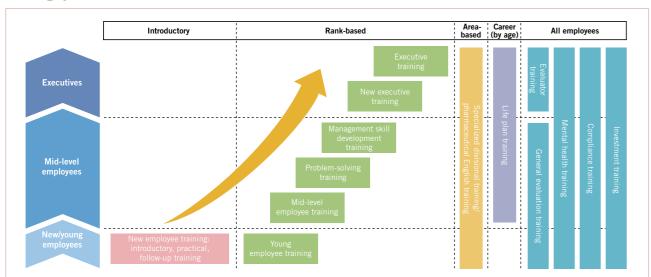
In the fiscal year ended March 31, 2021 (fiscal 2020), we instituted a work-from-home system as an option for diversifying work styles. Other objectives for introducing this system were to increase productivity though greater operational efficiency and create a means of maintaining continuity of operations in the event of a disaster.

Employees used an average of 83.0% of paid leave in fiscal 2022. From fiscal 2007 to fiscal 2022. 100% of staff who left work for childcare reasons returned, and the

The Human Resources Seikagaku Seeks

https://www.seikagaku.co.jp/en/sustainability/

Training systems



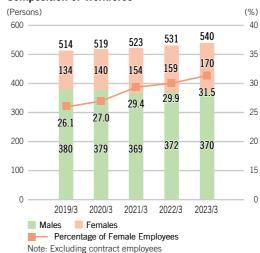
number of male employees taking childcare leave has also increased. Furthermore, Seikagaku creates employee friendly workplaces through staff assignments that correspond to the nature and amount of work, improvement of workplace environments, and by limiting long working hours.

Diversity management

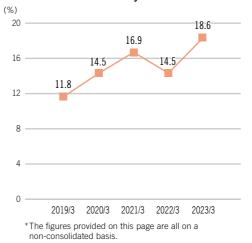
Seikagaku is creating an environment and developing systems, programs, and mechanisms to enable female employees to fully demonstrate their capabilities and is implementing measures to support the advancement of women as part of diversity management efforts.

In the diversity and inclusion project, implemented from 2020 to 2022, to ensure that the contributions and successes of diverse employees are the driver of Seikagaku's sustained growth, we set concrete targets for each business site and proceeded with reforms to create an organization in which individuals can demonstrate their full potential. Going forward, we will engage in initiatives for "Promotion of diversity and development of human resources," one of Seikagaku's material issues, and

Composition of Workforce



Executive Positions Held by Women



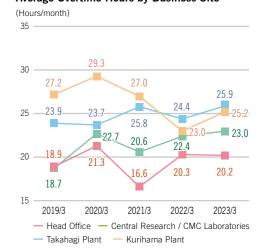
continue efforts to create an organization in which all employees can fully demonstrate their capabilities.

In October 2022, we revised the previous single-track personnel promotion system to a multiple-track system to make possible personnel assignment and development that take aptitude into account.

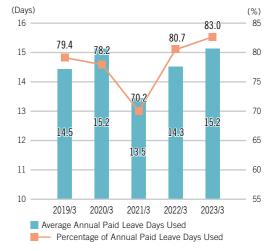
Mental healthcare

Since 2009, Seikagaku has implemented measures aimed at maintaining the physical and mental health of employees to vitalize workplaces and increase productivity. Specifically, we are improving the overall workplace environment by obtaining the advice and assistance of industrial physicians and public health nurses periodically and as needed, by conducting mental health care seminars for managers that utilize the results of annual stress checks, and other means. We have also instituted an external hotline and counseling service that employees and family members can freely utilize and are developing a self-care support system to enable employees themselves to recognize physical disorders and stress and learn how to cope with them.

Average Overtime Hours by Business Site



Use of Paid Leave





Corporate Governance

Members of the Board (as of June 20, 2023)

Directors



President & CEO Ken Mizutani

Term of office as Director: 33 years				
	ber of thes owned	e Company's l:	465,640 shares	
Apr.	1970	Joined Mitsubishi Chemical (current Mitsubishi Chemica		
Aug.	1988	Joined the Company		
June	1990	Member of the Board, Head Biologicals and Diagnostics		
June	1993	Member of the Board, Senio President responsible for Pl Manufacturing		
June	1998	Member of the Board, Senio President responsible for M		
June	2000	Member of the Board, Senio President and Head of Cent Laboratory		
June	2002	Representative Director and Board, Senior Executive Vic responsible for Pharmaceut Chemicals, Oral Care, Glyco Central Research Laborator	e President iicals, Fine iforum, and Head of	
June	2005	Representative Director and Board, President & Chief Ex		
June	2018	Representative Director and Board, President & CEO and Manufacturing		
June	2019	Representative Director and Board, President & CEO (cu		



Toshiyuki Okada

	ber of t	he Company's ed:	16,601 shares	
Apr.	1989	Joined Dow Corning Japan	n Co., Ltd.	
Sept.	1996	Joined Johnson & Johnso (current Johnson & Johns	ii iiioaioai itti itti	
Feb.	2015	Vice President and Chief	Technology Officer	
Sept.	2015	Joined the Company Executive Vice President, for Quality Assurance, Pha Regulatory Affairs Auditing	armacovigilance an	
June	2016	Executive Vice President r Quality Assurance, Pharm Regulatory Affairs Auditing	acovigilance and	
Jan.	2017	Executive Vice President r Marketing	esponsible for	
June	2017	Member of the Board, Exe President responsible for I		
June	2018	Member of the Board, Exe President responsible for I Development & Marketing	Business	
June	2023	Member of the Board, Exe President responsible for l Assurance (current position	Reliability	



Yosuke Funakoshi

	Term of office as Director:		5 years	
	Number of the Company's shares owned:		17,201 shares	
June.	1990 2008 2012	Joined ONO PHARMACE Joined Takeda Pharmace Takeda Global Research & Inc. (current Takeda Deve Americas, Inc.)	utical Company Limi & Development Cent	
Aug.	2014	Vice President of Strategic Joined the Company Senior Vice President and Executive Vice President	d assistant to Senior	
Oct.	2014	Research & Development Senior Vice President and Clinical Development	t .	
June	2016	Executive Vice President, Research & Development Development		
June	2017	Executive Vice President Research & Development Development		
June	2018	Member of the Board, Extresponsible for Research Head of Clinical Developm	& Development and	
Oct.	2021	Member of the Board, Extresponsible for Research (current position)		





Audit & Supervisory Board Member

Ioru	Takeda

	01 01110	ce as Director:	7 years
	es owne	the Company's ed:	2,200 shares
Apr.	1983	Joined The Long-Term Credi Limited (current SBI Shinsei	
Oct.	2000	Joined The Industrial Bank ((current Mizuho Bank, Ltd.)	of Japan, Limited
Oct.	2008	General Manager, Risk Mana Department, Mizuho Trust &	
Apr.	2012	Corporate Auditor (full-time)	
Apr.	2016	Joined the Company as Seni	or Vice President
June	2016	Audit & Supervisory Board N (current position)	Member



Mikako Torii

Term of office as Director: Number of the Company's	1 yea	
shares owned:	14,059 shares	

Apr. 1988 Joined the Company
June 2011 Head of Corporate Staff
June 2015 Executive Vice President and Head of
Corporate Staff June 2022 Audit & Supervisory Board Member (current position)



Shinkichi Matsuo Term of office as Audit & Supervisory Board Member: 4 years

Outside Audit & Supervisory Board Member

	ber of t	the Company's ed: —
Apr.	1991	Joined Mitsubishi Electric Corporation
Apr.	1993	Joined Yokohama City Government
Oct.	1995	Joined Ota Showa Audit Corporation (current Ernst & Young ShinNihon LLC)
Apr.	1999	Registered as a certified public accountant
June	2018	Representative Director, NextLeap Co., Ltd. (current position)
June	2019	Outside Audit & Supervisory Board Member of the Company (current position)



Outside Member of the Board Mio Minaki

Num		te as Director: 4 years the Company's ed: —
Apr.	1999	Joined MIT Corporation
Oct.	2003	Public prosecutor, Tokyo District Public Prosecutors Office
Apr.	2004	Public prosecutor, Osaka District Public Prosecutors Office
Apr.	2005	Public prosecutor, Fukuoka District Public Prosecutors Office
Apr.	2014	Litigation Department Attorney, Ministry of Justice Fukuoka Legal Affairs Bureau
Apr.	2016	Public prosecutor, Tokyo District Public Prosecutors Office
Apr.	2017	Assigned as Head of Legal Affairs Department to Agriculture, forestry and fisheries Fund corporation for Innovation, Value-chain and Expansion Japan
Apr.	2019	Admitted to the bar in Japan
Apr.	2019	Joined Minaki & Kitazawa Law Office (current position)
June	2019	Outside Director of the Company (current position)



Outside Member of the Board Yasuyuki Sugiura

Nun		te as Director: 2 year the Company's ed: -
Apr.	1978	Joined Mitsubishi Corporation
Apr.	1998	General Manager, Washington Office, Mitsubishi International Corporation
Apr.	2006	CFO and SVP in charge of Corporate Department, Mitsubishi International Corporation
Apr.	2009	Executive Officer and General Manager, Corporate Communications Department, Corporate Strategy & Planning Division
Apr.	2012	President & Director and Head of Chicago Branch, Mitsubishi International Corporation
Apr.	2013	Executive Vice President, Mitsubishi Corporation and President & Director, Mitsubishi Corporation (Americas)
Apr.	2016	Advisor, Mitsubishi Corporation (current position)
June	2017	Managing Director, Toyo Bunko (current position)
June	2021	Outside Director of the Company (current position)



Outside Audit & Supervisory Board Member Takayuki Maruyama

Term of office as Audit & Supervisory

d Mem	ber: 3 years
	he Company's d: –
2000	Admitted to the bar in Japan
2000	Joined Nagashima Ohno & Tsunematsu
2005	Joined Smith, Anderson, Blount, Dorsett, Mitchell & Jernigan, LLP
2006	Admitted to the bar in New York State, US
2008	Joined OH-EBASHI LPC & PARTNERS (current position)
2020	Outside Audit & Supervisory Board Member of the Company (current position)



Outside Audit & Supervisory Board Member Wakako Mitani (New election)

Term of office as Audit & Supervisory Board Member: Number of the Company's shares owned:

Apr.	2000	Admitted to the bar in Japan
July	2001	Joined Tanabe & Partners (current pos
June	2023	Outside Audit & Supervisory Board Me of the Company (current position)



Executive Vice Presidents

Overseas subsidiaries, Marketing Activity Supervision, Glycoscience Networking and Medical Affairs Executive Vice President

Yuji Shimojima

Head of Production Executive Vice President

Masayuki Ito

HR, F&A and Corporate Staff Executive Vice President

Kazushi Takeda

Business Development & Marketing Executive Vice President

Ryoji Tomokiyo

- 1. Ken Mizutani, Toshiyuki Okada, and Yosuke Funakoshi
- concurrently serve as Executive Vice President.

 2. Terms of office are as of June 20, 2023.
- 3. Number of the Company's shares owned is as of March 31, 2023.

Basic concept

In accordance with the management creed. "We create safe and useful products for human well-being with basic research based on glycoscience" and on the basis of profound awareness of our social mission and responsibilities as a pharmaceutical company, Seikagaku seeks to increase the speed of transparent and fair decision-making and strengthen oversight of business execution and is focusing on development of internal control systems, including for compliance and risk management. Our policy is to aim for sustainable growth and corporate value enhancement by striving to further strengthen corporate governance, which we view as an important management priority, and building a management system that rewards the trust of our shareholders and other stakeholders, and of society at large, through these initiatives.

Corporate governance structure

The Company has adopted a Company with an Audit & Supervisory Board governance system, having determined that the most effective and appropriate form of corporate governance for the Company is for the Board of Directors to oversee business execution and for the Audit & Supervisory Board to perform auditing and

oversight in cooperation with the accounting auditor and Audit Department. Furthermore, the Company has introduced an executive vice president system to separate management oversight by the Board of Directors from business execution and, in accordance with the basic policy determined by the Board of Directors, as a rule holds weekly Management Committee meetings to discuss important management matters.

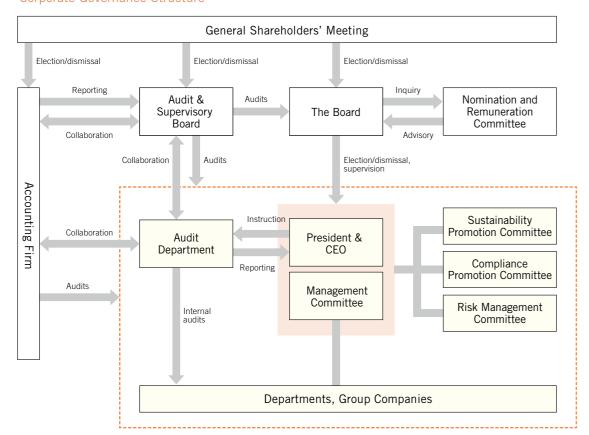
The Board of Directors has established the Nomination and Remuneration Committee, comprising the president & CEO and all outside members of the Board, to advise on matters concerning selection of candidates for members of the Board and Audit & Supervisory Board members, remuneration for members of the Board, etc.

The Sustainability Promotion Committee discusses the policy on sustainability-related activities, promotion measures, and other matters and supervises their implementation, and the Compliance Committee discusses promotion measures to improve compliance effectiveness. The Risk Management Committee appropriately manages business risks and implements risk prevention measures.

Board of Directors

The Board of Directors comprises five members, including two outside members of the Board. The Company aims to enhance management oversight from an independent

Corporate Governance Structure



standpoint by appointing outside members of the Board to one-third or more of the Board seats.

To decide important matters stipulated in laws and regulations, the Articles of Incorporation, and rules for the Board, such as formulation of basic management policy, the mid-term management plan, and the annual management plan and the election of executive vice presidents, and to supervise business execution, in principle the Board holds regular monthly meetings and extraordinary meetings convened as necessary.

In fiscal 2022, the Board mainly deliberated matters related to management strategy, such as the mid-term management plan, important business strategies, and capital policy; matters related to sustainability, such as the TCFD recommendations and materiality; matters related to the settlement of accounts; matters related to corporate officers and remuneration; and matters related to subsidiaries.

To enable sufficient deliberation at Board meetings, as a rule, materials on matters for resolution and reporting matters are distributed to the Board members at least three days before meetings to provide time to review the materials.

Also, advance explanations of important agenda items are provided, as well as additional materials and supplemental explanations upon request.

A meeting of outside officers, comprising two outside members of the Board and three outside Audit & Supervisory Board members, undertakes improvement of Board operation by periodically analyzing and evaluating the effectiveness of the Board of Directors and reporting the results to the Board.

Both outside members of the Board are reported to the Tokyo Stock Exchange, Inc. as independent officers by the Company.

Enhancing functions of the Board of Directors

To achieve sustained growth and medium- and long-term enhancement of corporate value, following deliberation by the Nomination and Remuneration Committee, the Board of Directors determines skills required by the Board on the basis of basic management policy, the mid-term management plan, and other criteria. To maintain a structure capable of effectively fulfilling the Board's role and duties, the Board selects candidates for corporate officer positions taking into consideration their knowledge, experience, abilities, and character, in addition to identified skills and Board diversity. Since the skills required by the Board of Directors constantly change according to the business environment and other factors, the Company periodically reviews them.

The term of office for members of the Board is one year with the aim of creating a management structure that would be able to adapt quickly and flexibly to changes in the business environment.

The outside members of the Board are responsible for oversight from an objective standpoint, a perspective that incorporates the common interests of shareholders, and is based on expert knowledge and insights into corporate management. The outside members of the Board also attend meetings held among the president & CEO, Audit & Supervisory Board members, and heads of each department to share views of the Company's business issues and the external environment.

Main Expertise and Experience of Directors and Audit & Supervisory Board Members

Title	Name	Corporate management	Finance/ Accounting	Legal affairs/ Risk management	R&D	Global	Production/ Quality	Sustainability	Human Resources/ Diversity
President & CEO	Ken Mizutani	•		•	•		•	•	
Executive Vice President	Toshiyuki Okada	•			•	•	•	•	
Executive Vice President	Yosuke Funakoshi	•			•	•		•	
Outside Member of the Board	Mio Minaki			•					•
Outside Member of the Board	Yasuyuki Sugiura	•	•			•		•	•
Audit & Supervisory Board Member	Toru Takeda		•	•					
Audit & Supervisory Board Member	Mikako Torii			•				•	•
Outside Audit & Supervisory Board Member	Shinkichi Matsuo	•	•						
Outside Audit & Supervisory Board Member	Takayuki Maruyama			•		•			
Outside Audit & Supervisory Board Member	Wakako Mitani			•					•

Audit & Supervisory Board

The Audit & Supervisory Board, comprising five members, including three outside members, audits and supervises the execution of director's duties by each member of the Board

Audit & Supervisory Board members attend meetings of the Board of Directors, offer advice and recommendations as necessary, interview directors in charge and corporate officers of subsidiaries in accordance with an annual plan, and exchange views with the president & CEO. Furthermore, they have periodic meetings with the accounting auditor and Audit Department and receive audit reports, audit results, and other reports, exchange views, and strive for cooperation.

The full-time members attend Management Committee meetings and other important meetings; examine minutes, approval documents, and other important documents; perform audits of business sites; and share information about business execution and development of the internal control system and confirmation of its status of operation with the outside members at Audit & Supervisory Board meetings.

The outside members perform the role of auditing and supervising the Board members' execution of duties from an objective standpoint, a perspective that incorporates the common interests of shareholders, based on expert knowledge and insights into corporate management. All three outside Audit & Supervisory Board members are reported to the Tokyo Stock Exchange, Inc. as independent officers by the Company.

Nomination and Remuneration Committee

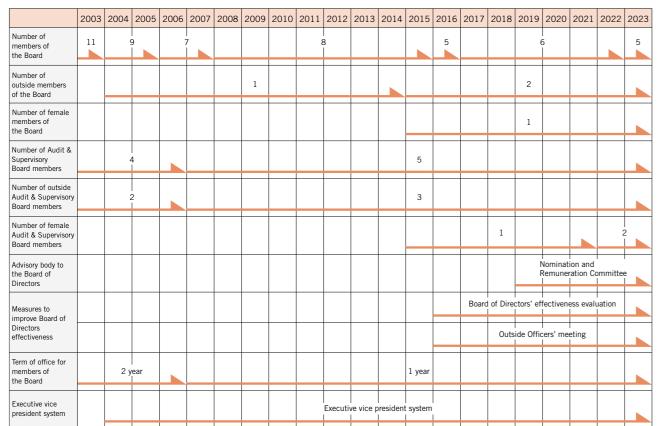
To increase fairness, transparency, and objectivity relating to matters including the selection of candidates for members of the Board and Audit & Supervisory Board and determination of remuneration for members of the Board and enhance corporate governance, Seikagaku has established the Nomination and Remuneration Committee as a voluntary advisory body to the Board. The Committee comprises the president & CEO and both outside members of the Board, and the Company believes that appointing outside Board members as a majority of Committee members ensures independence.

The Committee deliberates and reports to the Board of Directors on its views on the composition of the Board, matters relating to the selection and dismissal of members of the Board and Audit & Supervisory Board members, and matters relating to remuneration for members of the Board. It also discusses and decides the amounts of basic compensation, performance-linked compensation, and earnings-linked compensation for members of the Board as well as matters for which decision-making has been delegated by the Board of Directors.

In fiscal 2022, the Committee deliberated matters relating to the selection of candidates for members of the Board and determination of remuneration for members of the Board, the amounts of monetary remuneration for individual members of the Board (including evaluation of each Board member pertaining to performance-linked compensation), and other matters.

Initiatives to Strengthen Corporate Governance

(Fiscal 2023)



Status of Holding of Board of Directors and Other Meetings (Fiscal 2022)

Organizational body	Composition	Frequency of convocation	Purpose
The Board*1	Members of the Board: 5 (including 2 outside members of the Board)	Once monthly in principle	The Board of Directors decides important matters stipulated in laws, the Articles of Incorporation and the Board of Directors Regulations, and oversees business execution. The Board of Directors met 14 times in fiscal 2022.
Audit & Supervisory Board	Audit & Supervisory Board members: 5 (including 3 outside members of the Board)	Once monthly in principle	The Audit & Supervisory Board discusses and decides important audit-related matters. The full-time members share information about business execution and development of the internal control system and its status of operation with the outside members at Audit & Supervisory Board meetings. The Audit & Supervisory Board met 14 times in fiscal 2022.
Nomination and Remuneration Committee	Members of the Board: 3 (including 2 outside members of the Board)	Meetings held as necessary	The Nomination and Remuneration Committee is a voluntary advisory body to the Board of Directors that reports to the Board on matters about which the Board has sought consultation, such as the nomination of candidates for corporate officer positions and remuneration for members of the Board and decides matters delegated by the Board. The majority of the committee members are independent outside members of the Board. The committee met three times in fiscal 2022.
Management Committee	Members of the Board: 3 Executive vice presidents: 4 Full-time Audit & Supervisory Board members: 2*2	Once weekly in principle	The Management Committee confers agendas of executive functions they have been tasked for implementation by the Board, based on the basic policy of the Board. The Management Committee met 42 times in fiscal 2022.

^{*1} Audit & Supervisory Board members also attend meetings of the Board of Directors.
*2 Observers

Reasons for Election and Main Expertise of Outside Members of the Board and Outside Audit & Supervisory Board Members

Category	Name	Reasons for election
Outside member	Mio Minaki	Ms. Mio Minaki has a wealth of experience developed over many years in the judicial field and insight relating to corporate legal affairs as a lawyer. The Company has judged that she is capable of appropriately fulfilling the role of outside member of the Board from a professional standpoint based on this knowledge and experience.
of the Board Yasuyuki Sugiura		Mr. Yasuyuki Sugiura has been involved in corporate management for many years at a general trading company, mainly in the U.S. and Canada, and has a wealth of international experience and wide-ranging insight. The Company has judged that he is capable of appropriately fulfilling the role of outside member of the Board by reflecting this experience and insight in the Company's management.
	Shinkichi Matsuo	Mr. Shinkichi Matsuo is highly knowledgeable in finance and accounting as a certified public accountant and also has a wealth of experience relating to corporate management. The Company has judged that he is capable of appropriately performing a management oversight role from a professional standpoint based on this knowledge and experience.
Outside Audit & Supervisory Board member	Takayuki Maruyama	As a lawyer, Mr. Takayuki Maruyama has expertise in corporate restructuring, business revitalization, and international contracts. The Company has judged that he is capable of appropriately performing a management oversight role from a professional standpoint based on this knowledge and experience.
Wakako Mitani		As a lawyer, Ms. Wakako Mitani has abundant insight with regard to corporate legal affairs, centered on labor issues, in addition to governance in the medical care field and medical care-related administration. The Company has judged that she is capable of appropriately performing a management oversight role from a professional standpoint based on this knowledge and experience.

Main Activities of the Outside Members of the Board (Fiscal 2022)

Category	Name	Main activities
Mio Minaki		Ms. Mio Minaki offered advice and recommendations on numerous occasions at meetings of the Board of Directors from an independent, objective point of view based on a wealth of experience in the legal field and professional insight into corporate legal affairs. In her capacity as a member of the Nomination and Remuneration Committee, she attended all three Committee meetings and actively offered advice and recommendations in discussions about selection of candidates for members of the Board, determination of remuneration for members of the Board, identification of skills necessary for the Board, and other matters.
Outside member of the Board	Yasuyuki Sugiura	Mr. Sugiura offered advice and recommendations on numerous occasions at meetings of the Board of Directors from an independent, objective point of view based on a wide range of insights obtained through a wealth of management experience and international experience at a general trading company. In his capacity as a member of the Nomination and Remuneration Committee, he attended all three Committee meetings held after he took office and actively offered advice and recommendations in discussions about selection of candidates for members of the Board, determination of remuneration for members of the Board, identification of skills necessary for the Board, and other matters.
	Shinkichi Matsuo	Mr. Shinkichi Matsuo actively expressed opinions at Audit & Supervisory Board meetings from an independent, objective point of view based on professional insight into finance and accounting accumulated over many years. In addition, he received reports from the full-time Audit & Supervisory Board members, accounting auditor, and Audit Department, and increased the effectiveness of auditing by gathering information through interviews with the president & CEO, corporate officers in charge, and corporate officers of subsidiaries. He also attended meetings of the Board of Directors and offered advice and recommendations on numerous occasions from an expert point of view.
Outside Audit & Supervisory Board member	Takayuki Maruyama	Mr. Takayuki Maruyama actively expressed opinions at Audit & Supervisory Board meetings from an independent, objective point of view based on professional insight, mainly concerning corporate restructuring and international contracts. In addition, he received reports from the full-time Audit & Supervisory Board members, accounting auditor, and Audit Department, and increased the effectiveness of auditing by gathering information through interviews with the president & CEO, corporate officers in charge, and corporate officers of subsidiaries. He also attended meetings of the Board of Directors and offered advice and recommendations on numerous occasions from an expert point of view.
	Wakako Mitani	Appointed on June 20, 2023

Board of Directors' effectiveness analysis and evaluation

At Seikagaku, a meeting of outside officers, comprising the outside members of the Board and outside Audit & Supervisory Board members, analyzes and evaluates the effectiveness of the Board of Directors on the basis of the content of a questionnaire survey conducted prior to the evaluation and reports the results of evaluation and points for improvement to the Board.

The evaluation for fiscal 2022 confirmed that decision-making on important matters and oversight of business execution functioned properly and that effectiveness of the Board of Directors was sufficiently ensured by providing advance explanations concerning important Board meeting agenda items and explanations

of the proceedings of the Management Committee and other internal organizations.

To help activate deliberation, Seikagaku provides opportunities for sharing management issues and other matters with the outside officers and as a rule distributes materials at least three days before Board meetings to ensure sufficient time to review them beforehand.

Proposals for improvement included setting up a forum for meetings between outside officers and departments in charge concerning matters such as sustainability and the mid-term management plan, and the Board will respond to these proposals.

A message from a newly appointed Audit & Supervisory Board member



Outside Audit & Supervisory Board Member **Wakako Mitani**

Contributing to appropriate management and effective business operation that meet the expectations of society

In my role as an outside Audit & Supervisory Board member, I deepened my understanding of Seikagaku's business and management by not only attending meetings of the Board of Directors and Audit & Supervisory Board, but also by periodically conducting interviews concerning the current state of the business, such as receiving summaries of Seikagaku's business operations from individual managers. Also, I participated at presentations on research themes and open discussions held in July 2023 at the Central Research Laboratory (see "TATENO Forum" on page 27) and saw for myself Seikagaku employees vigorously

discussing not only already commercialized pharmaceuticals, but also numerous research themes still at the basic research stage.

On another subject, in recent years we have seen many examples of companies subjected to harsh social opprobrium and thrown into management crises not necessarily because of illegalities, but for improprieties, and it is necessary to beware of risks beyond risks associated with legal compliance. Since pharmaceutical companies in particular are subject to enormous societal expectations, in addition to the strict regulations applying up to now, appropriate management and business operation that reflect concern for all stakeholders are required.

I will do my utmost to contribute to sound corporate development that meets the needs of society by bringing an outside perspective and drawing on my experience as a lawyer involved with the healthcare industry, while respecting Seikagaku's goals and the corporate culture cultivated over many years.

Compensation for corporate officers

At a meeting held on February 5, 2021, the Board of Directors resolved to adopt the Policy for Determining the Details of Individual Remuneration for Members of the Board and Audit & Supervisory Board Members, and Seikagaku now operates a compensation scheme in accordance with this policy. At the time of Board of Directors resolutions pertaining to compensation for corporate officers, the Board consults with the Nomination and Remuneration Committee beforehand and receives a report concerning the details of matters to be resolved.

Basic policy

The Company's basic policy on compensation for directors (excluding outside members of the Board; the same applies hereinafter in this section "Compensation for corporate officers"), is to maintain a compensation structure designed to contribute to sustained earnings improvement by increasing incentives for directors to meet the expectations of shareholders. Specifically, compensation consists of basic compensation; earnings-linked compensation and performance-linked compensation, which serve as short-term incentives; and restricted stock compensation, which serves as a long-term incentive

Compensation for outside members of the Board and Audit & Supervisory Board members consists of basic compensation only, in view of their role of management oversight independent from business execution.

Overview of types of compensation

The following is an overview of the types of compensation. <Basic compensation (monthly monetary compensation)>
The amount of compensation for members of the Board is determined taking into consideration the balance between the going rate, management performance, and employee salaries. The amount of compensation for outside members of the Board and Audit & Supervisory Board members is determined by making reference to the going rate.

<Performance-linked compensation (monthly monetary compensation)>

Performance-linked compensation is determined through qualitative assessment based on achievement by each director of objectives for the previous fiscal year pertaining to important measures in the mid-term management plan. Qualitative assessment according to level of achievement is a three-stage to five-stage assessment, and the amount is calculated according to each assessment by multiplying basic compensation by a predetermined coefficient.

<Earnings-linked compensation (monthly monetary compensation)>

SKK EBITDA* is used as an indicator, and the amount of compensation is determined based on SKK EBITDA from the previous fiscal year. Assessment using SKK EBITDA is a three-stage evaluation, and the amount is calculated by multiplying basic compensation by a predetermined coefficient according to the assessment of each member of the Board.

*SKK EBITDA is Seikagaku's own profit indicator consisting of operating income plus depreciation expense. The Company has selected SKK EBITDA because it considers it appropriate as a short-term incentive with respect to business performance each fiscal year. Actual SKK EBITDA for fiscal 2022 was ¥3,441 million

<Restricted stock compensation (non-monetary compensation)>

Restricted stock compensation, which involves the granting each year at a certain time of common shares of the Company for which transfer is restricted until retirement ("restricted stock"). Compensation paid for the granting of restricted stock is a monetary claim, and the amount is calculated by multiplying the basic compensation of each member of the Board by a fixed rate for each position.

Policy on the ratio of each type of compensation for members of the Board

Compensation for members of the Board is designed so that the ratio of earnings-linked compensation increases the higher the position, taking into consideration the results of an external survey and using as a benchmark compensation levels at other companies similar in size to Seikagaku or in the same industry.

The Board of Directors receives a report from the Nomination and Remuneration Committee and reviews compensation design from time to time, taking into consideration factors such as the business environment and the Company's medium- to long-term trend in business performance.

The ratio of each type of compensation for members of the Board is roughly as follows in the case of maximum target achievement.

Basic compensation : 70–80%
Performance-linked compensation: 10%
Earnings-linked compensation : 5–10%
Restricted stock compensation : 5–10%

By a resolution of the Board of Directors, monetary compensation for individual full-time and outside members of the Board is delegated to the Nomination and Remuneration Committee. The Committee's authority extends to determination of the amount of basic compensation, the amount of performance-linked compensation (including assessment of each director), and the amount of earnings-linked compensation. The reason for delegation of this authority is so that the Nomination and Remuneration Committee, on the basis of the expert knowledge and insights into corporate management of the outside members of the Board, to determine the amount of monetary compensation for individuals from an objective standpoint, a perspective that includes the common interests of the shareholders.

Evaluation coefficients pertaining to performance-linked compensation, as well as evaluation categories and evaluation coefficients pertaining to earnings-linked compensation, are determined beforehand by the Board of Directors, giving respect to the content of a report from the Nomination and Remuneration Committee. With regard to restricted stock compensation, a form of non-monetary compensation, the timing of payment and method of distribution of monetary compensation claims are determined by the Board of Directors, giving respect to the content of a report from the Nomination and Remuneration Committee.

Compensation for Audit & Supervisory Board members is determined through discussion among them.

Measures to facilitate the exercise of voting rights

To ensure that shareholders are able to secure sufficient time for consideration of General Shareholders' Meeting proposals, the Company strives for early sending out and disclosure of the Notice of Convocation. For the 77th General Shareholders' Meeting, held on June 20, 2023, the Company disclosed the Notice of Convocation on the Tokyo Stock Exchange, Inc. website and the Seikagaku corporate website seven days before the statutory due date (four weeks before the meeting). The Company sent out the Notice of Convocation on May 29, 2023, three weeks before the meeting.

For foreign shareholders, the Company prepares an English translation of the Notice of Convocation and posts the English version on the corporate website at the same time as the Japanese version. Furthermore, the Company has responded to the diversification of methods of exercising voting rights by adopting electronic methods, including the Electronic Voting Platform for Foreign and Institutional Investors, in addition to voting in writing.

The Company has introduced measures to help increase shareholder understanding at the General Shareholders' Meeting, such as by using video and narration to provide business reports and explanations of shareholder proposals. The Company also discloses on its website a summary of the visual content of the business report provided at the General Shareholders' Meeting.

Total Amount of Compensation for Each Category of Officer, Total Amount by Type of Compensation, and Number of Relevant Officers (Fiscal 2022)

Officer estagen	Total compensation		Number of			
Officer category	(Millions of yen)	Basic compensation	Performance-linked compensation	Earnings-linked compensation	Restricted-stock compensation	officers
Members of the Board (excluding outside members of the Board)	212	180	14	3	13	4
Outside members of the Board	18	18	_	_	_	2
Total	231	199	14	3	13	6
Audit & Supervisory Board members (excluding outside officers)	46	46	_	_	_	3
Outside Audit & Supervisory Board members	23	23	_	_	_	3
Total	69	69	_	_	_	6
Grand total	300	269	14	3	13	12

Notes: 1. Based on the status at the time of adjournment of the 76th Ordinary General Shareholders' Meeting, held on June 21, 2022, one retired outside Audit & Supervisory Board members is included in the table above.

2. The amount of pay for a member of the Board does not include the employee portion of salary of someone who is concurrently an employee and a member of the Board.

3. Stock compensation is the amount of compensation claims in respect of restricted stock compensation.

5. The total amount of compensation paid to all Audit & Supervisory Board members was resolved at the 61st Ordinary General Shareholders' Meeting held on June 22, 2007, to be no more than ¥80 million per year. Five persons were eligible at the time of the shareholders' meeting resolution.

Cross-shareholdings policy

The Company strategically holds shares of other companies only when it is deemed to contribute to the enhancement of the Company's corporate value over the medium to long term on the basis of comprehensive consideration of business strategy, business relationships, and other factors.

The Financial Asset Management Committee, comprising the members of the Board, the corporate officer in charge of administration, and the managers of the Finance & Accounting Department and Corporate Planning Department, verifies each year whether the shareholding purpose and benefits and risks associated with the holdings are appropriate, and the Board of Directors evaluates the verification results. The Company's policy is to reduce any shareholding whose holding rationale is deemed unacceptable by the Board.

The Company makes decisions regarding voting rights of cross-shareholdings from the perspective of whether the content of shareholder proposals conforms to the abovementioned shareholding policy by contributing to the enhancement of the Company's corporate value over the medium to long term. In addition, financial results and other business conditions of investee companies and careful examination of whether or not the proposals contribute to increasing the shareholder value of these companies are considered.

Policies concerning constructive dialogue with shareholders and investors

The Company places importance on constructive dialogue with shareholders and investors for the purpose of realizing sustained growth and enhancement of corporate value over the medium to long term.

The Company has named the member of the corporate officer in charge of administration as the officer in charge of investor relations and has assigned a person in charge of corporate communication to the Corporate Staff Department. The person in charge of corporate communication has developed a system that makes possible appropriate and fair disclosure by striving to gather and share information through the holding of regular and ad hoc meetings with the Finance & Accounting Department, the Research & Development Division, the Business Development & Marketing Division, and other interested divisions and departments.

As a rule, when the Company receives requests for interviews or other forms of dialogue, an appropriate person is selected according to the purpose and promptly responds. In fiscal 2022, the Company held 70 interviews or other interactions with shareholders and investors. The content of dialogues and opinions or requests obtained through such interactions are shared internally through reporting at meetings of the Board of Directors and Management Council as appropriate and through submission of quarterly IR activities reports to the members of the Board and managers of interested departments.

In addition, the Company holds biannual financial results briefings for institutional investors, securities analysts, and the media. The president & CEO provides a review of operations, progress in R&D, measures to improve shareholder value, and other updates. The Company also strives to provide information in a more understandable manner by posting audio files, presentation materials, etc. from the financial results briefings on the corporate website thereby enhancing content for individual investors. Furthermore, the Company follows the Fair Disclosure Rules and rigorously manages insider information and disclosure information under the provisions of the Company's Insider Trading Prevention Regulations and Disclosure Policy. Additionally, the Company designates the period from the day following the quarterly closing date until the time of the announcement of the financial results as a quiet period to prevent financial information from leaking during the preparations for the announcement. During the quiet period, Seikagaku refrains from answering questions or making comments about financial results. However, the Company responds to inquiries about information that has already been published.

Measures to achieve management mindful of capital cost and share price

The Company's capital policy is to determine the Company's cost of capital yearly and report it to the Board of Directors. The Company assesses the business potential of major investment projects based on project capital cost, and investment decisions are made by the Board of Directors.

The Company has instituted a mid-term management plan covering the four-year period beginning with the fiscal year ending March 31, 2023. With regard to maximizing the product value of SI-6603 (a treatment for lumbar disc herniation), a key measure in the management plan, the Company has obtained positive results in a Phase III clinical study being conducted in the U.S. (an additional study). The Company aims to increase corporate value in the medium and long term and enhance its reputation in capital markets by steadily proceeding with preparations for an early new drug application and product launch and achieving the numerical targets for fiscal 2026, the final year of the management plan (net sales of ¥40.0 billion and operating income of ¥7.0 billion).

^{4.} The total amount of compensation paid to all members of the Board was resolved at the 61st Ordinary General Shareholders' Meeting held on June 22, 2007, to be no more than ¥400 million per year (of which the outside members of the Board proportion shall be no more than ¥50 million per year). (Seven persons were eligible at the time of the shareholders' meeting resolution.) Also, the amount of compensation for separately granting restricted stock to directors (excluding outside members of the Board) was resolved at the 73rd Ordinary General Shareholders' Meeting held on June 19, 2019 to be no more than ¥50 million per year, and the total number of restricted stock shares issued or divested for granting to eligible members of the Board set at no more than 40,000 shares. Four persons were eligible at the time of the shareholders' meeting resolution.

Materiality 4 Compliance and Risk Management

Compliance

To ensure high ethical standards across all aspects of corporate activities as required of a pharmaceutical company, Seikagaku has positioned honest and fair behavior as the basis of all activities. This involves not only complying with strict laws and regulations, but also putting into practice the principle of "Conducting oneself in a disciplined manner in accordance with morals and also courageously correcting the misdeeds of others."

To embody these ideals, Seikagaku has instituted a compliance program (including the SKK Group Compliance Code of Conduct) based on the Creed and the Guidelines for Our Activities. To more appropriately and smoothly implement the program, Seikagaku has developed a compliance program implementation structure, established the Compliance Promotion Committee, and installed a compliance officer and compliance promotion officers. The Compliance Promotion Committee, which is chaired by the president & CEO and has the Management Committee members as its members, increases compliance effectiveness by promoting and implementing measures to increase compliance awareness on a company-wide level through an activity plan set every year.

Outline of the SKK Group Compliance Code of Conduct

As an employee of a life sciences company, each Seikagaku employee makes respect for life the primary consideration and behaves on the basis of high corporate ethical standards that earn the trust and support of society.

For details on the Compliance Program, please visit the Seikagaku corporate website.



https://www.seikagaku.co.jp/en/corporate/compliance.html

Compliance

Seikagaku instills compliance by distributing to all employees the Compliance Program Handbook, which sets down compliance standards, procedures, and a promotion framework, and the Compliance Card, which summarizes key points of employee behavior.

コンプライアンスカード

を整備をコンプライアンス

当社は「独創公正 多に情勢」の影響場からた、独創的な医薬局等の創業を通じて世界の人水の健康でも受かな生活に貢献していきます。経営網板を反映したコンプライアンス・プログラムは、当社の行動の基本がおしなるものです。
私たちは、生命限策企業に求められる場合等を表守して、減失かつ公正に行動します。・当社コンプライアンスト担税より

少生化学工業株式会社

Compliance Card

Compliance education and training

In other measures to promote compliance, Seikagaku provides internal training on specific compliance-related themes every fiscal year to constantly raise compliance awareness. Seikagaku made "Reaffirming the importance of compliance throughout the company and strengthening and putting into practice the compliance promotion structure" an action policy and engaged in compliance promotion activities, including online training and e-learning.

Diagram of Implementation Structure



Compliance Promotion Officers

Head office department managers, plant managers, and site managers

*Associates of Cape Cod, Inc. and Dalton Chemical Laboratories, Inc. have developed their own compliance frameworks that conform to their local environments, laws, and regulations and have instituted a system of reporting important compliance-related incidents to Seikagaku following reporting to their respective boards of directors.

<Role of Compliance Promotion Committee>

The committee approves measures to promote compliance in accordance with the Compliance Program and supervises the status of their implementation

<Role of Compliance Promotion Officers>

They are responsible for implementing the Compliance Program in their respective divisions, carrying out self-inspections, and also implementing the resolutions of the Compliance Promotion Committee.

Consultation and reporting (whistleblowing) contact points

The Compliance Program is closely connected to appropriate business execution as well as maintenance of a worker-friendly workplace environment for employees.

In the interest of early detection of Compliance Program violations and suspected violations and the resolution of problems, Seikagaku has instituted hotline operation standards and has also set up a communications counseling system (male and female staff appointed at each business site) to respond to internal communication issues.

Furthermore, by establishing multiple internal and external consultation contact points, such as utilization of an external whistleblowing channel, Seikagaku has put in place an environment that enables persons seeking advice to use the contact point that makes them feel most at ease, depending on the problems they face or individual circumstances.

Seikagaku has also put in place the necessary mechanisms to comply with the amended Whistleblower Protection Act, and have ensured that all employees are aware of the whistleblower system's process and its importance.

Consultation and Reporting Route



Protection of employees who seek advice and whistleblowers

Seikagaku gives the highest priority to protecting the confidentiality and privacy of employees who seek advice and to whistleblowers. Information about employees who seek advice, whistleblowers, and those involved shall be disclosed on a need-to-know basis and their privacy and anonymity shall be protected. Seikagaku stipulates in its internal regulations that sufficient care must be taken to ensure that whistleblowers and those who have cooperated with investigations do not suffer any detriment as a result of speaking out.

Risk management

Seikagaku has established Corporate Risk Management Regulations and developed a structure for monitoring and managing risks related to the execution of business operations. The President has overall responsibility for managing corporate risk, while officers and general managers are responsible for properly managing risks and preventing risks from being realized in the operations under their jurisdiction.



Risk management structure

Seikagaku has also established a Risk Management Committee, which deliberates and establishes company-wide risk management policies and preventive measures. When a new major risk emerges, the Risk Management Committee is also responsible for setting up a task force immediately and implementing countermeasures to minimize any damage.

The occurrence of an emergency, the establishment of a task force, the response policy, and the implemented response measures are reported to the Board of Directors.

Risk Management Structure



Consolidated 10-year Summary

(Millions of yen / %)

										(Millions of yen / %)
	2014/3	2015/3	2016/3	2017/3	2018/3	2019/3	2020/3	2021/3	2022/3	2023/3
Net Sales*1	27,586	27,589	29,211	28,321	31,434	27,559	29,206	27,734	34,851	33,456
Overseas Sales*1	8,569	9,753	11,530	11,319	12,281	12,098	13,205	14,361	17,918	20,048
Cost of Sales	11,223	12,130	12,871	13,247	13,008	13,114	12,513	12,112	14,323	15,432
Selling, General and Administrative Expenses*1	11,319	12,833	13,833	13,113	13,872	12,727	12,796	13,372	16,033	15,910
R&D Expenses	6,588	8,146	8,649	7,834	8,408	7,148	6,877	7,209	9,005	7,951
Operating Income*1	5,043	2,624	2,506	1,960	4,552	1,718	3,896	2,248	4,495	2,114
Ordinary Income	5,878	4,008	3,500	2,477	5,327	2,859	3,981	3,024	5,395	3,069
Net Income	4,745	3,650	2,578	1,787	3,922	2,244	(10,839)	4,262	3,733	2,236
Total Equity	64,785	70,410	69,815	70,646	73,945	73,036	59,767	63,604	66,340	67,216
Total Assets	73,826	80,889	80,218	80,048	84,098	80,238	68,746	69,915	75,244	75,625
Overseas Sales Ratio (Excluding Royalty Income)*1	30.8	34.8	38.7	38.7	41.5	43.8	46.8	50.5	56.6	59.9
Cost of Sales Ratio (Excluding Royalty Income)*1	40.8	44.4	44.6	47.9	46.0	48.9	45.9	44.8	46.4	46.1
Selling, General and Administrative Expenses Ratio*1	41.0	46.5	47.4	46.3	44.1	46.2	43.8	48.2	46.0	47.6
R&D Expenses Ratio (Excluding Royalty Income)*1	24.0	29.8	30.0	28.3	29.7	26.7	25.2	26.7	29.2	23.8
Operating Income Ratio*1	18.3	9.5	8.6	6.9	14.5	6.2	13.3	8.1	12.9	6.3
Ordinary Income Ratio*1	21.3	14.5	12.0	8.7	16.9	10.4	13.6	10.9	15.5	9.2
Net Income Ratio	17.2	13.2	8.8	6.3	12.5	8.1		15.4	10.7	6.7
Return on Equity (ROE)*2	7.5	5.4	3.7	2.5	5.4	3.1	_	6.9	5.7	3.3
Return on Assets (ROA)*2	8.1	5.2	4.3	3.1	6.5	3.5	5.3	4.4	7.4	4.1
Turnover of Total Assets*2	0.41	0.38	0.38	0.37	0.37	0.35	0.39	0.40	0.48	0.44
Shareholders' Equity Ratio	87.8	87.0	87.0	88.3	87.9	91.0	86.9	91.0	88.2	88.9
Number of R&D Personnel	215	216	221	222	233	233	242	231	223	196
R&D Personnel Ratio	33.6	33.3	33.3	32.3	32.5	31.3	27.9	25.3	23.8	20.0
Number of Employees	639	649	663	687	718	744	868	913	937	976*3
Amount of Capital Expenditure	7,222	2,095	1,975	1,173	1,591	1,310	2,109	2,127	2,194	2,091
Depreciation and Amortization	1,767	2,610	3,191	2,920	2,925	2,902	1,778	808	1,051	1,327
Net Income per Share	83.55	64.27	45.39	31.55	69.30	39.76	(192.15)	75.54	66.32	40.49
Total Equity per Share	1,140.48	1,239.51	1,229.05	1,248.07	1,306.37	1,294.88	1,059.40	1,127.14	1,179.46	1,232.41
Dividends per Share	26.00	26.00	26.00	31.00*4	26.00	26.00	26.00	24.00*5	30.00*6	26.00
Dividend Payout Ratio	31.1	40.5	57.3	98.3	37.5	65.4	_	31.8	45.2	64.2
Dividends as a Percentage of Total Equity (DOE)	2.3	2.2	2.1	2.5	2.0	2.0	2.2	2.2	2.6	2.2

^{*1} New revenue recognition standard has been applied retroactively to fiscal 2013-fiscal 2020 figures.

*2 Total Equity and Total Assets are average amounts of the numbers for the end of previous FY and the end of current FY, respectively.

*3 Excluding executive vice presidents.

*4 Including a 70th anniversary commemorative dividend of ¥5 per share.

*6 Including a JOYCLU approval commemorative dividend of ¥4 per share.

*7 Including a JOYCLU launch special dividend of ¥10 per share.

Review of Operations (April 1, 2022–March 31, 2023)

Overall net sales and income

In the fiscal year ended March 31, 2023 (fiscal 2022), net sales were ¥33,456 million, down 4.0% year on year. The result is attributable to a substantial decline in royalty income and a decline in sales in the pharmaceutical business due to the impact of National Health Insurance (NHI) drug price reductions in Japan, despite the positive impact of yen depreciation on the results from the LAL business and overseas pharmaceuticals.

Operating income fell 53.0% year on year to ¥2,114 million as a result of the sales decrease, notwithstanding a decrease in R&D expenses accompanying completion of subject enrollment in an additional clinical study in the U.S. for SI-6603, a treatment for lumbar disc herniation. Ordinary income and net income attributable to owners of parent fell 43.1% to ¥3,069 million and 40.1% to ¥2,236 million, respectively.

(Millions of yen)

	2022/3	2023/3	Year on Year
Net Sales	34,851	33,456	-4.0%
Operating Income	4,495	2,114	-53.0%
Ordinary Income	5,395	3,069	-43.1%
Net Income	3,733	2,236	-40.1%
R&D Expenses	9,005	7,951	-11.7%

Pharmaceuticals business

The Pharmaceuticals business is the core business of our company, which manufactures and sells pharmaceuticals, medical devices, and bulk products based on glycoconjugates such as hyaluronic acid. In the Pharmaceuticals business, net sales decreased 11.6% year on year to ¥22,723 million, accounting for 67.9% of total sales.

Domestic Pharmaceuticals (¥11,271 million, down 1.5% year on year)

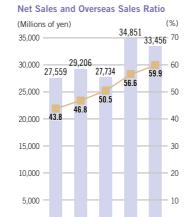
Deliveries to medical institutions of ARTZ, a joint function improvement agent for knee osteoarthritis, increased year on year thanks to successful measures to promote switching from competing products. The Company's sales fell due to the impact of NHI drug price reductions, despite an increase in shipment volume due to higher deliveries to medical institutions and the impact of shipment timing.

The Company's sales of the joint function improvement agent JOYCLU increased year on year, reflecting higher deliveries to medical institutions. The Company issued a Dear Healthcare Professionals Letter of Rapid Safety Communication (Blue Letter) about JOYCLU on June 1, 2021 and is continuing cooperative efforts with sales partner Ono Pharmaceutical Co., Ltd. to proactively gather side effects reports and other information and provide safety-related information. Also, since April 2022 the Company has been conducting a clinical study to identify the cause of side effects with the cooperation of specialists and medical institutions.

Deliveries to medical institutions of the OPEGAN series of ophthalmic viscoelastic devices increased year on year due to a gradual return to the pre-COVID market growth trend and the impact of limited shipments of competing products. The Company's sales were at the prior-year level as a result of shipment volume increase, despite the impact of NHI drug price reductions.

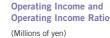
The Company's sales of MucoUp, a submucosal injection agent for endoscopic surgery, decreased due to the impact of an NHI reimbursement price revision.

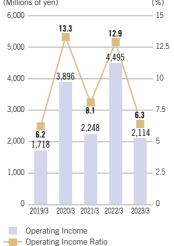
Although deliveries to medical institutions of HERNICORE, a treatment for lumbar



Net Sales Overseas Sales Ratio (Excluding Royalty Income)

0 2019/3 2020/3 2021/3 2022/3 2023/3





Pharmaceuticals Business Sales



disc herniation, remained at the prior-year level, the Company's sales rose due to the impact of shipment timing.

Overseas Pharmaceuticals (¥8,534 million, up 11.5% year on year)

Local sales volume in the U.S. of Gel-One, an intra-articular single-injection viscosupplement for the treatment of knee osteoarthritis, decreased year on year, reflecting the impact of a health insurance system change implemented in July 2022. The Company's sales increased substantially, fueled by the impact of yen depreciation.

Local sales volume in the U.S. of SUPARTZ FX, an intra-articular 5-injection viscosupplement for the treatment of knee osteoarthritis, rose due to a changing market environment accompanying a health insurance system change. The Company's sales increased, reflecting the impact of yen depreciation.

Local sales volume in China of ARTZ fell sharply because of the impact of factors including limitation of access to outpatient services accompanying the renewed spread of COVID-19. The Company's sales declined substantially, reflecting the absence of shipments in the first quarter due to a packaging material change and a decrease in local sales volume.

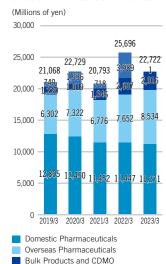
Bulk Products and Contract Development and Manufacturing Organization (¥2,916 million, up 11.9% year on year)

Sales increased due to higher sales of bulk products and the impact of yen depreciation on sales of contract development and manufacturing and other services of overseas subsidiary Dalton Chemical Laboratories, Inc.

Royalty Income (¥100 million, down 100.0% year on year)

Royalty income has significantly decreased. Beginning in fiscal 2021, royalty income has been reclassified from non-operating income to net sales.

Sales of Pharmaceuticals Business



Royalty Income

LAL business

We manufacture and sell endotoxin-detecting reagents used in the quality control of pharmaceuticals and medical devices in Japan and overseas. Net sales of LAL business for the fiscal year under review were ¥10,732 million, up 17.2% from the previous fiscal year.

LAL Business

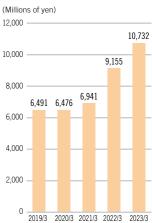
Sales from the LAL business segment increased, reflecting the impact of ven depreciation on sales of reagents and diagnostics at overseas subsidiary Associates of Cape Cod, Inc. as well as steady sales in Japan.

(Millions o	of yen)
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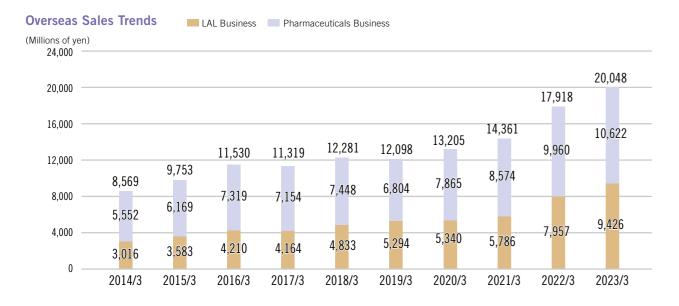


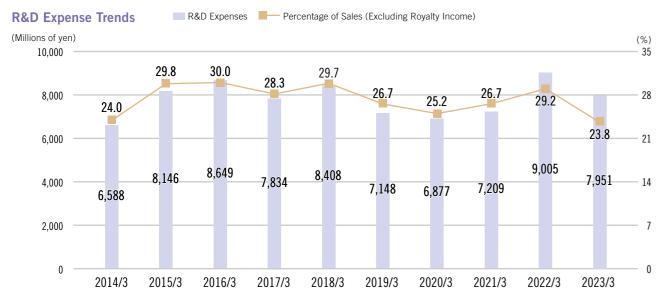




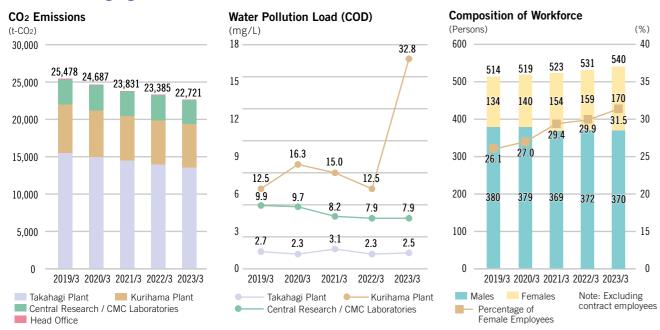


Financial/Non-financial Highlights





Non-financial Highlights (Non-consolidated Basis)



Overseas Subsidiaries

Associates of Cape Cod. Inc. (Massachusetts, USA)

Associates of Cape Cod, Inc. (ACC), a wholly owned subsidiary of Seikagaku, was the first FDA-licensed LAL manufacturer in the world.

It was established in 1974, became a Seikagaku subsidiary in 1997, and currently plays a central role in the global Bacterial Endotoxin Testing (BET) and clinical glucan detection sectors. ACC employs approximately 290 employees and has operations in the U.K. and Germany.

ACC's reagent and diagnostics production facility, located at their campus in Falmouth Technology Park in Massachusetts, is vertically integrated with an end-to-end manufacturing operation that extends from harvesting horseshoe crab blood cells, a reagent raw material, to manufacturing, testing, packaging/labeling and distributing endotoxin and glucan in vitro diagnostic agents. From the perspective of promoting the appropriate use of natural resources and biodiversity, we have also recently focused on the manufacture and sale of gene-recombinant endotoxin-detecting reagents (see P07) without the blood harvested from horseshoe crabs.

Corporate Outline (As of March 31, 2023)

Paid-in Capital	\$2,080
Ownership Ratio	100%
Business	Manufacturing and sales of reagents and diagnostics
URL	https://www.acciusa.com



Dalton Chemical Laboratories, Inc. (Ontario, Canada

Dalton Chemical Laboratories, Inc., which became a Seikagaku subsidiary in March 2020, is a company that provides services including contract development and manufacturing (CDMO) services for pharmaceutical companies, such as manufacturing of chemical synthetics and pharmaceutical ingredients as well as manufacturing process development. Dalton was established in 1986 and has a U.S. and Canadian GMP*1—compliant manufacturing site for pharmaceuticals and other products in Ontario, Canada. Dalton currently has approximately 150 employees.

Seikagaku will utilize Dalton's chemical synthesis technologies and expertise in manufacturing process development in its new drug development. In addition, Seikagaku will transfer the manufacturing of investigational drugs and some Seikagaku products to Dalton, as well as switch from the outsourced manufacturing of chemical synthetics used for research and other purposes to in-house production by Dalton.

*1 GMP: Good Manufacturing Practice Standards for manufacturing control and quality control in manufacturing.

Corporate Outline (As of March 31, 2023)

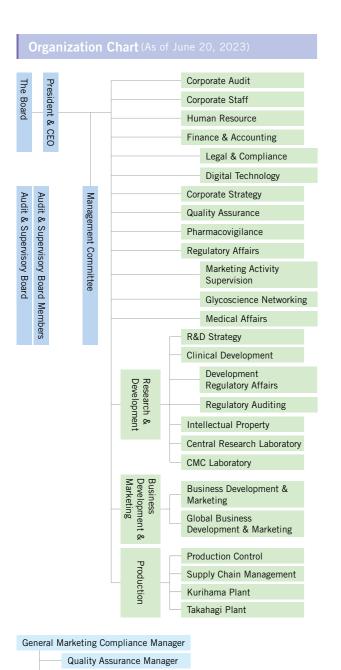
Paid-in Capital	CAD 49,800 thousand
Ownership Ratio	100%*2
Business	CDMO
URL	https://www.dalton.com/



^{*2} Dalton is a wholly owned subsidiary of SKK CANADA ENTERPRISES CORPORATION, an intermediate holding company established in Canada by Seikagaku

Corporate Data

Overview (As of March 31,	2023)
Company Name	SEIKAGAKU CORPORATION
President	Ken Mizutani
Establishment	June 2, 1947
Business Activities	Manufacturing and sales of pharmaceuticals and medical devices specifically related to glycoconjugates
Fiscal Year	April 1 to March 31
Stock Exchange Listing	Tokyo Stock Exchange, Prime Market (Stock code: 4548)
URL	https://www.seikagaku.co.jp/en/
Number of Employees	976 (Consolidated/Excluding executive vice presidents)
Paid-in Capital	¥3,840 million
Net Sales	¥33,456 million (As of March 31, 2023)



Safety Management Manager

Locations	
Head Office	Marunouchi Center Building 6-1, Marunouchi 1-chome Chiyoda-ku Tokyo 100-0005, Japan Tel: (81) 3-5220-8950
Central Research Laboratory/ CMC Laboratory	1253, Tateno 3-chome Higashiyamato-shi Tokyo 207-0021, Japan Tel: (81) 42-563-5811
Kurihama Plant	3-1, Kurihama 9-chome Yokosuka-shi Kanagawa 239-0831, Japan Tel: (81) 46-835-3311
Takahagi Plant	258-5, Aza-Matsukubo Oaza-Akahama Takahagi-shi Ibaraki 318-0001, Japan Tel: (81) 293-23-1181

Major Subsidiaries

ASSOCIATES OF CAPE COD, INC.

124 Bernard E. Saint Jean Drive, East Falmouth MA 02536-4445 U.S.A. Tel: (1) 508-540-3444

DALTON CHEMICAL LABORATORIES, INC.

349 Wildcat Rd. Toronto, ON M3J 2S3 CANADA Tel: (1) 416-661-2102 / (1) 800-567-5060

Stock Information

Stock Information (As of March 31, 2023)		
Shares per Unit	100	
Authorized Shares	234,000,000	
Authorized Outstanding Shares	56,889,871	
Number of Shareholders	10,285	
General Shareholders' Meeting	June	
Date of Record for Shareholders Eligible to Receive Dividends	March 31	

Shareholder Registry Administrator

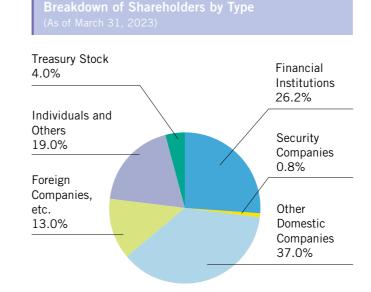
Mitsubishi UFJ Trust and Banking Corporation

<Contact>

Mitsubishi UFJ Trust and Banking Corporation Securities Agency Division PO Box 29, New Tokyo Post Office, Tokyo 137-8081 Tel: 0120-232-711 (Domestic toll-free)

Major Shareholders (As of March 31, 2023)		
Name of Shareholders	Number of Shares Held (Thousands of Shares)	Percentage of Outstanding Shares (%)
1 Shingyo KK	7,843	14.4
2 The Master Trust Bank of Japan, Ltd. (Trust account)	7,724	14.2
3 KK Kaiseisha	7,293	13.4
4 Custody Bank of Japan, Ltd. as Trustee for Mizuho Bank, Ltd. Retirement Benefit Trust Account re-entrusted by Mizuho Trust and Banking Co, Ltd.	1,573	2.9
5 MUFG Bank, Ltd.	1,536	2.8
6 The Bank of New York Mellon (International) Limited 131800	1,470	2.7
7 Custody Bank of Japan, Ltd. (Trust account)	1,324	2.4
8 Kaken Pharmaceutical Co., Ltd.	1,207	2.2
9 Mizutani Foundation for Glycoscience	828	1.5
10 Meiji Yasuda Life Insurance Company	688	1.3

 $Note: Treasury\ stock\ (2,273\ thousand\ shares)\ is\ excluded\ from\ the\ calculations\ of\ the\ percentages\ above$



Corporate Logo



The main motif of Seikagaku's corporate logo is a chain, which symbolizes our decades-long commitment to sugar chain R&D. The closely interlocked links represent the strong bonds that exist between science and industry, between people and people, and between a rich natural environment and an enriching life. The links also symbolize Seikagaku's emphasis on partnership with society.

The overall shape of the logo as an oval stretched toward the upper right represents Seikagaku's corporate stance of aiming for infinite growth.

The blue brand color in the corporate logo symbolizes creativity and innovation, while the black projects an impression of strength.



SEIKAGAKU CORPORATION

Marunouchi Center Building 6-1, Marunouchi 1-chome, Chiyoda-ku Tokyo 100-0005, Japan

TEL: (81) 3-5220-8950 FAX: (81) 3-5220-8951

URL: https://www.seikagaku.co.jp/en/

