SEIKAGAKU CORPORATE REPORT 2020

INNOVATIVE THINKING

SEIKAGAKU CORPORATION

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.

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.

Key roles of sugar chains

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**
   Sugar 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.

Sugar chains and diseases

1. **Viral and bacterial infections**
   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.

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.

1 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.

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.

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 25% to 30% of net sales, and that 45%* of our employees are involved in R&D.

*Non-consolidated base

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 2020 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 2019 (April 1, 2019–March 31, 2020), but it also includes references to activities in fiscal 2020.

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.

1940s~ The world's first company to successfully produce chondroitin sulfate on a commercial scale.

1970s~ Pharmaceuticals using hyaluronic acid are developed.

1990s~ Enhances its range of pharmaceuticals using hyaluronic acid and expands its activities in overseas markets.

2018~ Product diversification leveraging cutting-edge glycoscience technology. Toward a new stage.

Major Product Timeline

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® as the first Japanese-made ophthalmic viscoelastic device

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
Launch of ARTZ Dispo®, a joint function improving agent

1995
Launch of OPEGAN Hi®, an 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
Launch of Gel-One®, an intra-articular single-injection viscosupplement for the treatment of knee osteoarthritis, in the U.S.

2016
Launch of SHELLGAN®, an ophthalmic viscoelastic device

2018
Launch of HERNICORE®, a treatment for lumbar disc herniation

2019
Launch of HyLink®, an intra-articular single-injection viscosupplement for the treatment of knee osteoarthritis in Italy

Business Structure Timeline

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.

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 (now the JASDAQ).

1997
Seikagaku Corporation acquires Associates of Cape Cod, Inc. (U.S.A.).

1998
ISO 13485 certification is achieved.

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).

2020
Seikagaku acquires CDMO* 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.

Net Sales (Millions of yen)

35,000
30,000
25,000
20,000
15,000
10,000
5,000

1950 1960 1970 1980 1990 2000 2010 2020

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

- Unmet medical needs*
  * Situations in which healthcare needs are not met or there are healthcare needs relating to diseases for which there are no effective treatment methods.
- Super-aging society
- Rising healthcare costs
- Locomotive syndrome
  * Locomotive syndrome: Reduced mobility due to disorders affecting locomotion, such as the knee joints and hip joints. These disorders are regarded as one of the factors that can reduce healthy life expectancy.

Assets

Human capital

Highly qualified personnel

Intellectual capital

Compound library and advanced knowledge relating to glycoscience

Manufacturing capital

Production and quality control systems to ensure the reliable supply of products

Financial capital

A stable financial base as a source of funding for drug discovery

Sources of competitiveness

Specialization in R&D and manufacturing

- Lean organizational structure with no pharmaceutical marketing units
- R&D investment equivalent to 25-30% of net sales

Glycoscience

State-of-the-Art Technology related to GAG

- Advanced manufacturing basic technologies, including extraction, purification, cultivation and modification technologies
- The ability to create diverse new pharmaceuticals based on the use of GAG and related enzymes

* GAG: Glycosaminoglycans (one of the components of glycoconjugates), such as hyaluronic acid and chondroitin sulfate

Output
Products and services

Innovative, high-quality pharmaceuticals and medical devices, etc.

«Ethical pharmaceuticals, medical devices»

Seikagaku contributes to healthcare in Japan and overseas by supplying ethical pharmaceuticals and medical devices based on GAG, such as hyaluronic acid and chondroitin sulfate, which are both structural components of glycoconjugates, and enzymes that act on GAG.

<Products for the treatment of orthopedic disorders>

- ARTZ® series: Joint function improving agent
- GEL-ONE®, Hylink®: Intra-articular single-injection viscosupplement
- HERNICORE®: Treatment for lumbar disc herniation

<Ophthalmic products>

- OPEGAN®, OPEGAN Hi®: Ophthalmic viscoelastic device
- SHELLGAN®: Ophthalmic viscoelastic device

<Other products>

- MucoUp®: Submucosal injection agent for endoscopic surgery
- Bulk product: Sodium hyaluronate, sodium chondroitin sulfate
- CDMO services (contract development and manufacturing)

«LAL-related products»

Seikagaku supplies endotoxin-detecting reagents and other products to pharmaceutical manufacturers, primarily for use in quality control in manufacturing processes for pharmaceuticals and medical devices.

- Endotoxin-detecting reagents
- Endotoxin-detecting equipment

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Business flow

R&D P23 → Production P29 → Marketing (through sales partners) P31 → Medical institutions / Patients

Quality compliance P33

Business risks

- Healthcare system reforms (including drug price system changes)
- Reliance on specific distributors and products
- Time and expense required for new drug development
- Procurement of animal-derived substances and restrictions on their use

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Outcome

Value Proposition

Improvement of patients' quality of life (QOL)

Extension of healthy life expectancy

Minimization of treatment impacts on patients

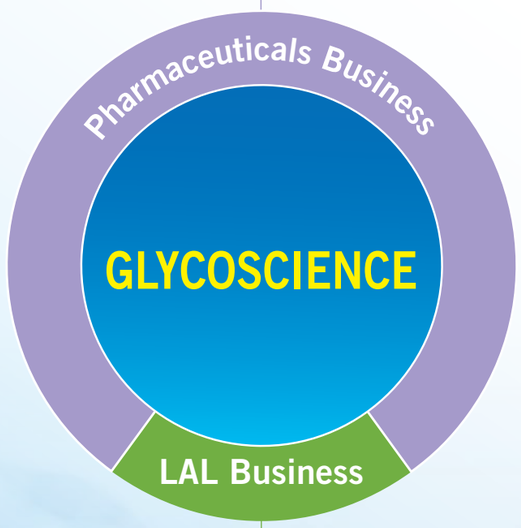
Further development and advancement of glycoscience

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.

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.



LAL Business

In addition to the Pharmaceuticals business, Seikagaku has the LAL business which provides endotoxin-detecting reagents and other related products.

What is the LAL business?

The main products of the LAL business are endotoxin-detecting reagents made from limulus amebocyte lysate (LAL), a substance extracted from the blood cells of horseshoe crabs.

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.

Joint Function Improving Agents

ARTZ®, ARTZ Dispo®, SUPARTZ FX®, VISCO-3™

ARTZ, a vial, containing hyaluronic acid as its main active pharmaceutical ingredient, became the world's first multiple-injection joint function improving agent. ARTZ Dispo is a prefilled syringe product*1 that saves the step of aspirating the drug solution into a syringe. These products have been approved and are supplied not only in Japan but also in overseas markets, including the U.S., Asia, and Europe.

*1 A kit with injectable syringe that have the solution been filled.

ARTZ Dispo®

Gel-One®, HyLink®

Gel-One is an intra-articular single-injection viscosupplement for the treatment of knee osteoarthritis, which contains cross-linked hyaluronate hydrogel as its main ingredient, originally developed for the U.S. market. Administration of only 3 mL provides long-lasting benefits. In March 2019, Seikagaku launched this product in Italy with its brand name "HyLink." Seikagaku is expanding the sales of this unique product with multi branding strategy.

SUPARTZ FX®

Gel-One®

Treatment for Lumbar Disc Herniation

HERNICORE®

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

HERNICORE®

Ophthalmic Viscoelastic Devices (OVD)

OPEGAN®, OPEGAN Hi®, SHELLGAN®

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.

OPEGAN® series

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*2.

*2 Endoscopic Submucosal Dissection/Endoscopic Mucosal Resection

MucoUp®

CDMO*3

CDMO services (contract development and manufacturing)

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

*3 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.


Bulk products

Endotoxin-detecting Reagents

ENDOSPECY®, TOXICOLOR®, Pyrochrome®, etc.

The endotoxin-detecting reagents that Seikagaku produces with its own technologies are mainly used in quality control of injectable pharmaceuticals, biological products, and medical devices, manufacturing processes, and water quality control of dialysate used in artificial dialysis.

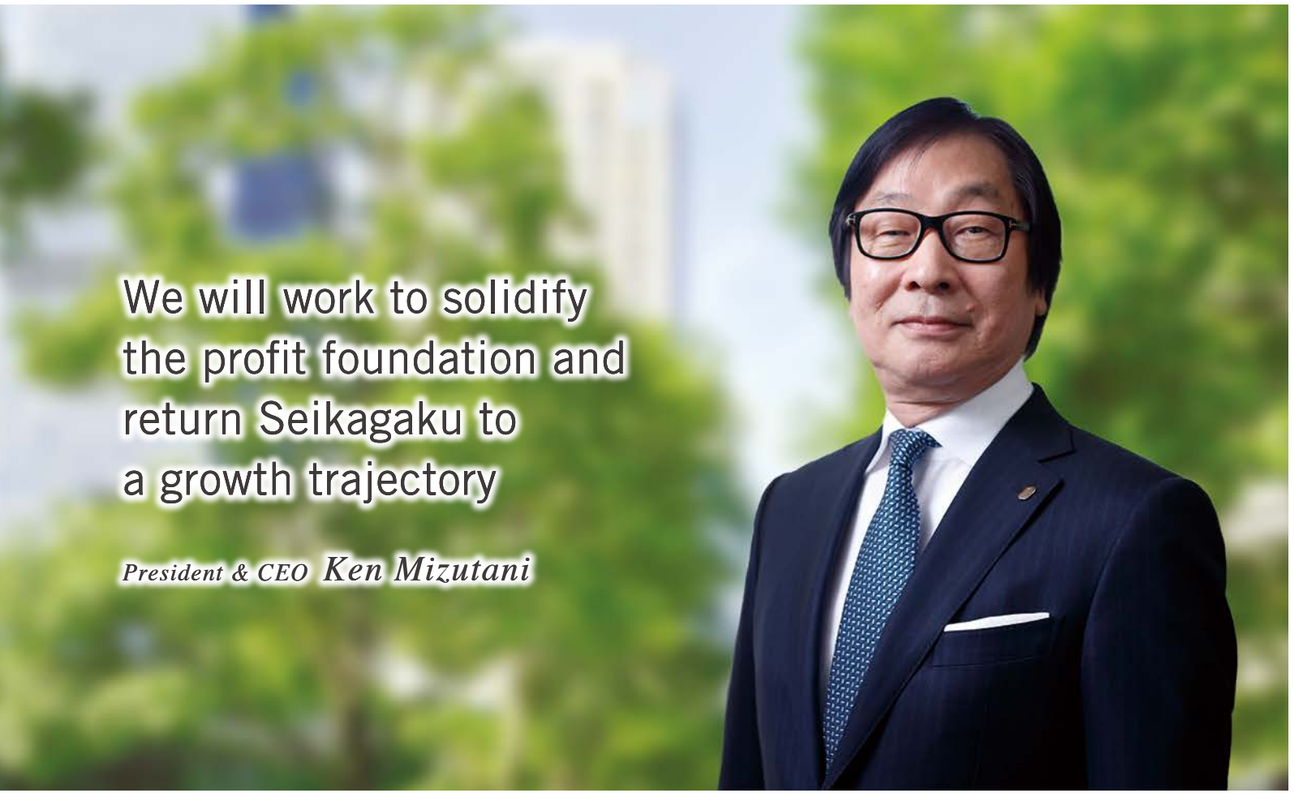
Endotoxin-detecting reagents

Endotoxin-detecting Devices

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.


Automatic endotoxin-detecting systems



The strategic positioning of the current mid-term management plan

Seikagaku Corporation faces a difficult business environment. Our mainstay products have been heavily affected by drug price reductions in Japan resulting from a drastic reform of the drug price system, and in the U.S. osteoarthritis market, the introduction of new competing products has intensified competition. In the area of new drug development, even as the entire industry faces the challenges of escalating R&D expenses and depletion of seeds for new drug development, the emergence of new therapeutic techniques, such as regenerative medicine and diversification of drug discovery modalities, are helping to propel the creation of new drugs. We consider it a pressing issue to respond to these challenges with a sense of urgency and undertake earnings improvement at an early date.

We have positioned the period of the current mid-term management plan, which covers the three-year period beginning in the fiscal year ended March 31, 2020 (fiscal 2019), as a time for solidifying our foundation in order to lay out a path for revived growth and are steadily implementing three important measures: 1) Accelerating new drug discovery to become the pillar of new profits, 2) Solidifying the profit foundation through market expansion of new products, and 3) Productivity improvement reforms. We will move forward with these measures with a sense of alacrity and unconstrained by existing frameworks and will build a strong foundation to support Seikagaku's future growth.

(Please refer to the section "Mid-term Management Plan" beginning on page 14 for details on the important measures.)

Our vision for Seikagaku from a medium- to long-term perspective

When formulating the mid-term management plan, we defined the vision Seikagaku will pursue from a medium- to long-term perspective as "A company that is valued by the world through its innovative drug discovery."

Seikagaku has unique knowledge and expertise in the field of glycoscience cultivated over many years, and we consider it our mission to utilize these strengths to continuously create innovative new drugs. We aim to enhance our value to society as a pharmaceutical company by contributing to the health and well-being of people around the world through the wider provision of new pharmaceuticals that patients truly need on a global scale. To achieve this, we consider it essential to not merely focus on short-term goals, but to also steadily pursue innovation from a medium- and long-term perspective in our day-to-day work, constantly keeping in mind the slogan of the mid-term management plan: "Innovative Thinking—Creating value based on innovative thinking."

The impact COVID-19 has had on Seikagaku

As you know, the spread of COVID-19 infections has caused enormous economic changes and drastic changes in people's lives all over the world. Seikagaku's business has been affected by declining sales of Seikagaku products due to factors including curtailment of outpatient services and delays in progress with R&D, mainly clinical trials. In these circumstances, we organized an emergency headquarters in March 2020 and have taken measures to minimize the impact of COVID-19 on our business while giving the highest priority to preventing the infection of our employees, their families, and local community. Continuity of production is a particularly important consideration. Pharmaceutical companies must fulfill the duty of ensuring the stable provision of pharmaceutical products and medical devices to patients. To accomplish this, we continue to operate our production plants while ensuring the safety of employees to the extent possible by implementing the best available measures to reduce contact among employees in the workplace.

At the same time, at departments and divisions where it is practicable, mainly at the head office, we recommend staggered working hours and have introduced working from home for the purpose of limiting the number of employees who work from company offices. This has led to major changes in people's work styles as well as a complete transformation of modes of work and communication methods. One outcome of this has been the ability to adapt to telework in a short time. We expect this situation to continue into the future and will prepare a system to facilitate work and enable employees to produce results by promptly addressing new challenges, such as the introduction of necessary HR programs and systems and IT development.

The forecast of financial results for fiscal 2020

Because it was difficult to prepare a reasonable forecast of financial results for the fiscal year ending March 31, 2021 (fiscal 2020) due to the impact of COVID-19, we decided not to announce a forecast in May 2020. We prepared and announced on September 24 a forecast in fiscal 2020 based on the first-quarter financial results and currently available information and forecasts.

Although sales performance in Japan and the United States, main markets for Seikagaku's business, was substantially affected by COVID-19 in the first quarter, in view of the fact that sales returned to approximately the prior-year level in July and August, we forecast that the negative impact of COVID-19 on Seikagaku's consolidated financial results will stay within a certain range. Net sales are forecast to decline compared to the prior year on lower first-quarter sales in Japan and overseas attributable to the spread of COVID-19 infections coupled with drug price reductions in Japan. Operating income is forecast to decline due to the sales decrease and higher expenses related to measures to promote subject enrollment in an additional clinical study underway in the United States for SI-6603, a treatment for lumbar disc herniation, despite a decrease in operating expenses in connection with a review of expenses related to sales promotion activities. Positive net income is expected as a result of non-recurrence of an extraordinary loss recorded in the previous fiscal year in connection with impairment of property, plant and equipment related to the Pharmaceuticals business.

Although it is unclear when the COVID-19 infections will subside, we have calculated this forecast based on the assumption that economic activity will not be severely restricted again. Going forward, we will carefully watch the infection situation and market trends, and ascertain their impact on the financial results in a timely and appropriate manner.

Forecast of consolidated financial results for fiscal 2020

(Millions of yen)

	2021/3 forecast	2020/3 Results	Change	% of Change
Net sales	26,650	28,642	(1,992)	–7.0%
Operating income	550	1,960	(1,410)	–71.9%
Ordinary income	1,400	3,981	(2,581)	–64.8%
Net income	1,150	(10,839)	11,989	—
R&D expenses [Ratio to net sales]	7,400 [27.8%]	6,877 [24.0%]	+522 [+3.8pt]	+7.6%

To our shareholders and other stakeholders

Our development pipelines progressed in fiscal 2019, the first of three years covered by the mid-term management plan, positioned as a time for solidifying our foundation in order to lay out a path for revived growth. For example, we submitted a new drug application for manufacturing and marketing approval in Japan for SI-613, an osteoarthritis treatment, and SI-722, a treatment for interstitial cystitis, advanced to the next stage of development. We concluded an agreement with Eisai Co., Ltd. on co-development of SI-613 and a marketing alliance in China, advancing preparations for multinational expansion of a product under development. Also, the acquisition of Dalton Chemical Laboratories, Inc. and its consolidation as a subsidiary for the purpose of diversifying the profit model has borne fruit. In this way, we have been able to achieve a certain measure of results with the important measures set forth in the mid-term management plan.

At the same time, the business environment facing Seikagaku is expected to remain difficult because of factors such as a worldwide trend of medical cost containment and uncertainty about when the COVID-19 infection will subside. These circumstances have further strengthened our awareness that prompt pursuit of profitability improvement is a matter of urgent importance, and we will continue to mount an all-out groupwide effort to construct a strong earnings foundation and return Seikagaku to a growth trajectory on the basis of an agile management strategy.

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.

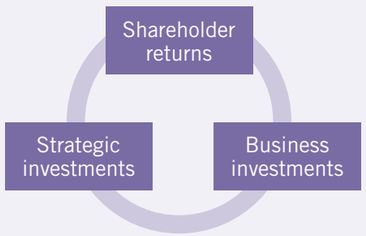
We request the continued understanding and support of our shareholders and other stakeholders in the coming years.

Basic policy on profit distributions

As a means of ensuing sustainable profit growth and improving corporate value, Seikagaku believes in the sharing of profits with its shareholders.

Seikagaku considers the return of profits to shareholders to be an important management challenge and has made paying dividends linked to business performance a basic policy. Also, Seikagaku will consider the purchase of treasury stock as appropriate, taking into consideration future business expansion and the total return ratio. In accordance with this policy, Seikagaku aimed for a dividend payout ratio of 50% for fiscal 2020 and 2021, taking into consideration business profits and other factors. However, with regard to the dividend forecast for fiscal 2020, Seikagaku intends to pay an annual dividend of ¥20 per share, representing a dividend payout ratio of 98.1% based on the earnings forecast, for continuing to hold Seikagaku shares notwithstanding the presence of a special factor, namely the spread of COVID-19.

We look forward to the continued support and guidance of our shareholders.



Shareholder returns	・Aiming for a 50% dividend payout ratio, taking into consideration business profits and other factors. ・Examining the purchase of treasury stock as appropriate.
Business investments	・Investing efficiently in R&D and production facilities etc. for creating new value.
Strategic investments	・Carrying out initiatives for strategic investments with prospects for future growth and synergies effect.

	Forecast for 2021/3	2020/3 Results
Net sales	¥10.00	¥13.00
Operating income	¥10.00	¥13.00
Ordinary income	¥20.00	¥26.00
Net income	98.1%	—

MID-TERM MANAGEMENT PLAN (FISCAL 2019–FISCAL 2021)

We have formulated a mid-term management plan with the aim of strengthening the foundation for re-establishing a growth path in response to the rapidly changing business environment. We will work on priority measures with innovative thinking without being bound by existing frameworks.

Corporate Slogan of the Mid-term Management Plan

INNOVATIVE THINKING

Creating value based on innovative thinking

<Our vision>
A company that is valued by the world through its innovative drug discovery

In pursuit of innovation
Applying glycoscience expertise to proprietary technology to have and realize the dreams and passions of innovative new drugs

Improvement of existing value
Based on fair and earnest business activities, continually providing products that are truly demanded for healthy and well-being of people around the the world

Acceleration of global market expansion
With our sights set upon the world, we cultivate new markets in R&D and products, leading to greatly enhanced profits

We will continue to create unique and original new drugs that are unique to our company, and provide them to patients more broadly and globally to increase the value of our existence as a pharmaceutical company.

[Our Three Important Measures]

1. Accelerating new drug discovery to become the pillar of new profits ▶ P17
2. Solidifying the profit foundation through market expansion of new products ▶ P19
3. Productivity improvement reforms ▶ P21

A period to solidify our foundation in order to lay out a path for revived growth

OUR THREE IMPORTANT MEASURES

A period to solidify our foundation in order to lay out a path for revived growth

We will work on three important measures for sustainable growth.

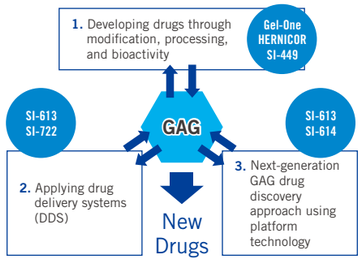
1. Accelerating new drug discovery to become the pillar of new profits ▶ P17

Strengthening and making use of the Company's own core technology related to GAGs*

Leveraging drug discovery technology held by Seikagaku to the fullest extent and raise the possibilities for innovative drug discovery.

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

Main technologies held by Seikagaku



Accelerating innovative drug discovery using an Open Innovation strategy

In addition to the technologies in its possession, Seikagaku will proactively undertake initiatives toward technology having high affinity with other companies, maximize synergies, and expand the number of projects in new drug development—all to speed up its work.

Steady expansion of the development pipeline with an eye toward global expansion

Seikagaku will quickly foster the development of SI-613, a treatment for osteoarthritis and enthesopathy, as a new core product by applying for and successfully obtaining drug approval, and by achieving launching. Seikagaku also aims to step up clinical studies for SI-722, a treatment for interstitial cystitis and bladder pain syndrome, and SI-449, an adhesion barrier. With regard to SI-6603, an indication for treatment for lumbar disc herniation, the Company will focus on speeding up additional study for the Phase III clinical study as it pursues a full effort toward a U.S. market launching.

2. Solidifying the profit foundation through market expansion for new products ▶ P19

Post-marketing drug development of HERNICORE in Japan

Seikagaku places priority on information provision activities to ensure appropriate use and safety as well as the collection of after-market safety information. Upon agreement with the authorities while coordinating with relevant scientific societies, the Company will work toward gradual expansion of requirements for available medical practitioners and facilities together with steady market penetration. The Company will also advance the disease awareness activities related to lumbar disc herniation for patients.

HERNICORE®, a treatment for lumbar disc herniation

Accelerating multinational expansion of existing products and products in development

By expediting the cultivation of new markets for existing products and products in development to maximize product value, Seikagaku seeks to solidify its medium- to long-term profit foundation. It will also be actively engaged in product improvement and application development in accordance with medical treatment needs in the targeted expansion regions.

Global expansion of endotoxin-detecting reagents that utilize genetic recombination technology

Overseas development of the Seikagaku Group's LAL business is under its U.S.-based subsidiary, the Associates of Cape Cod, Inc. (ACC). With expectations of future adoption, ACC aims for global expansion of gene-recombinant endotoxin-detecting reagents, leading to the securing of a new profit foundation.

3. Productivity improvement reforms ▶ P21

Thorough cost reductions

In manufacturing costs, as a result of a project that is already underway, Seikagaku will conduct a review of procurement costs and the optimization and streamlining of production, leading to greater assurance of product profitability. In selling, general and administrative expenses, the Company will improve work efficiency and make sure that thorough cost reductions are actually done. Furthermore, in order to carry out new drug development continuously, it will address efficient use of R&D expenses determined by priority.

Diversifying the profit model

Regardless of the business model up to now, the Company will carry out a vigorous examination of ways in which to produce new profit.

Creating an organization for maximizing the value of resources

Seikagaku will advance organizational reform that enables flexible responses to changes in the business environment and the nurturing of talent that can create new value, and which also lets each person demonstrate their potential to the fullest.

Dalton Chemical Laboratories, Inc., which became a subsidiary in March 2020.

Numerical targets

	2019/3 results	2022/3 targets
Net sales	¥28.3 billion	¥28.3 billion
Ordinary income	¥2.8 billion	¥4.5 billion
SKK EBITDA*	¥4.6 billion	¥5.0 billion
Overseas sales ratio	42.2%	50.0%

<Assumptions>
- Expansion of overseas sales in the LAL business makes up for the effects of the NHI drug price revisions in Japan
- Depreciation expense declines as a result of impairment accounting
- R&D expenses are 25–30% of sales
- Various royalty income is included as non-operating income
- Exchange rate: ¥105 to the U.S. dollar

*SKK EBITDA:
A profit indicator consisting of operating income plus depreciation expense and royalty income

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

Seikagaku's key strength in new drug development

At Seikagaku Corporation, research and development personnel, who account for approximately 45% of all employees (parent company basis), engage in new drug development. Seikagaku's key strength is specialized knowledge, technology, and expertise in the field of glycoscience accumulated over more than 70 years. In particular, we have leading-edge technological capabilities relating to glycosaminoglycans (GAGs), which are components of glycoconjugates, and take pride in being unsurpassed by competitors in unique drug-discovery technologies related to modified GAGs and GAG-related enzymes.

State of progress with development pipelines

The Research & Development Division is playing a central role in "accelerating new drug discovery as the pillar of new profits," one of three important measures set forth in the mid-term management plan, and is steadily achieving results. SI-613, a new drug for osteoarthritis, developed using a technology proprietary to Seikagaku, made a significant progress in the current mid-term management plan period.

SI-613 is a new drug in which hyaluronic acid and diclofenac (an anti-inflammatory agent) are chemically bound using Seikagaku's own proprietary technology. SI-613 is designed so that diclofenac is gradually released using a drug delivery system (DDS) to provide prompt and sustained relief of pain and inflammation associated with osteoarthritis. Further, since SI-613 is directly injected into the affected area as an injectable treatment, the risk of systemic side effects is expected to be low. Seikagaku submitted a new drug application for manufacturing and marketing approval in Japan in January 2020, and market introduction is expected during the period of the current mid-term management plan. In the U.S., SI-613 is in the Phase II clinical stage and is being developed for knee osteoarthritis, and we are proceeding with development in China as well. Seikagaku will steadily proceed with market introduction in Japan and further global development of SI-613 as a next-generation mainstay product.

Other drugs are steadily advancing through the development pipeline as well. SI-772, a treatment for interstitial cystitis and bladder pain syndrome that utilizes a GAG modification technology with a DDS, has been newly added to the pipeline, and development of SI-449, an adhesion barrier, has advanced to the pivotal study stage. As a result, our development pipeline has been visibly expanded.

On the other hand, a delay has occurred in the clinical trial plan for an additional Phase III clinical study in the U.S. of SI-6603, a treatment for lumbar disc herniation, due to application of stringent subject enrollment criteria to increase the probability of success. To respond to the delay, we are intensively implementing measures to increase the speed of subject enrollment, such as effective recruitment activities and an increase in the number of trial sites, and these measures are producing results.

Measures in response to the spread of COVID-19 infections

As mentioned above, we were able to achieve a measure of results in the first year of the current mid-term management plan. We consider further accelerating the R&D process in the remaining two years of the plan to be an important task going forward.

Nevertheless, as you know COVID-19 infections are spreading on a global scale, and discontinuation of clinical studies at some medical institutions and postponement of hospital visits by subjects are affecting the progress of clinical studies in Japan and overseas.

Seikagaku has moved quickly to review clinical trial protocols to ensure that sufficient attention is given to minimizing the risk of infection of patients and medical personnel participating in clinical studies. We are striving to progress clinical studies while giving due consideration to the risk of infection by means such as preparing procedure training videos and distributing them to trial sites as a substitute for site visits.

In conjunction with the Company's work-from-home recommendation, we are moving forward with measures at our laboratories such as the arrangement of working styles to concentrate on running experiments when working on-site and development of a system that makes possible data analysis from remote locations. In these difficult circumstances, each section is exercising ingenuity and working to minimize delays in the R&D process.

Creating research seeds from a long-term perspective

With regard to future research themes, there is no change in Seikagaku's stance of engaging in new drug development specialized in glycoscience. In the pharmaceuticals industry, where R&D expenses are trending upward more and more, we believe that it is important for Seikagaku to firmly plant its pivot foot in a business domain in which it excels and engage in efficient, agile research and development focused on target compounds and high-priority target diseases in order to speedily and continuously create new products. We must not only commercialize drugs currently in the development pipeline, but also accelerate creation of research seeds looking ten to twenty years out.

Based on this policy, under the current mid-term management plan, we are applying a drug discovery approach of utilizing open innovation in order to increase the number of projects. Combining technologies possessed by Seikagaku that we have cultivated over many years, such as GAG-related modification, processing, and bioactivity utilization technologies and technologies for application of substances to DDS, with technologies of other companies may boost the possibility of drug discovery. Furthermore, in addition to GAGs, we consider glycoscience, particularly the research and development of sugar chains, an important research theme. In this field, Seikagaku seeks to take advantage of a track record of collaboration with academic institutions based on the principle of industry-university partnership dating back to the Company's founding to elucidate sugar chain functions and pursue active involvement in new fields, such as gene therapy and cell therapy.

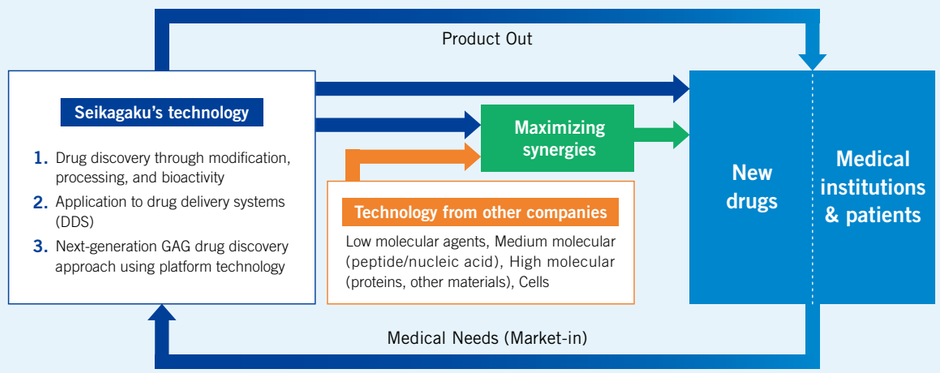
I take pride in being involved in drug discovery research and development in a field related to human life and the life sciences. I devote myself to day-to-day R&D activities while envisaging how the research we conduct can contribute to patients and imagining the smiling faces that will await us when we succeed in the projects we are currently pursuing. It is our mission to fully demonstrate our expertise and drug discovery capabilities to deliver new drugs that patients truly need.

We will utilize GAG-related knowledge and technology accumulated over many years to accelerate development of innovative new drugs.

Yosuke Funakoshi
Executive Vice President
Head of Research & Development Division
and Clinical Development

Accelerating Innovative Drug Discovery Using the Open Innovation Strategy

Speeding up and augmenting the number of projects through a drug discovery approach using Open Innovation



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

The business environment

Because Seikagaku Corporation's mainstay products in Japan are long-term listed drugs, they are heavily affected by price reductions resulting from a drastic reform of the drug reimbursement price system. The reimbursement price of ARTZ Dispo, a mainstay joint function improving agent for osteoarthritis, was reduced by 14.3% in the April 2018 reimbursement price revision, by 3.4% in the October 2019 reimbursement price revision accompanying the consumption tax increase, and by a further 13.1% in the April 2020 reimbursement price revision. Comparing this sharp reduction with the industry average, April 2020 reimbursement price reduction of 4.3% shows the magnitude of the impact on Seikagaku. To earn profits in this environment, we consider it an urgent task to increase sales of existing drugs in cooperation with our sales partners and to actively pursue overseas expansion and promptly undertake post-marketing development of new drugs.

Acceleration of overseas expansion

Seikagaku has identified two approaches to overseas expansion: further market penetration for products currently being sold, notably Gel-One, an intra-articular single-injection viscosupplement for the treatment of knee osteoarthritis, and opening up of new markets for existing products and new drugs in development.

Efforts to achieve further market penetration for existing products have produced results. Market share expansion measures for Gel-One in the U.S. implemented together with the sales partner have yielded good results, with an incentive plan targeting sales offices and sales representatives implemented in fiscal 2019 proving especially effective and resulting in an increase of approximately 30% on a local sales volume basis and record-high sales volume. We will continue to implement our sales strategy for further share expansion while closely watching changes in the medical system due to COVID-19 infections.

"Accelerating multinational expansion of existing products and products in development" is a measure set forth in the mid-term management plan, and we are working to open up markets to achieve this at an early date. Since this is a process involving the conduct of market demand surveys relating to existing products and new drugs in development as well as surveys on issues relating to competing products and pharmaceutical regulations and selection of sales partners, a certain amount of time will be required. At this time, several projects look to be taking shape. One accomplishment has been the conclusion in April 2020 of an agreement with Eisai Co., Ltd. concerning co-development and a marketing alliance in China for SI-613, an osteoarthritis treatment. I feel that SI-613 and other products in development are attracting a great deal of attention from overseas as new formulations. It is important to open up markets in a timely manner and strike while the iron is hot, and we will accelerate overseas expansion without missing our window of opportunity.

Accelerating Multinational Expansion of Existing Products and Products in Development

Solidifying the profit foundation by expanding business in existing products and products in development.

Post-marketing development of domestic pharmaceuticals

We recognize that post-marketing development of existing drugs is an important role for Seikagaku even as we open up new business fields through overseas expansion.

In Japan, post-marketing development of HERNICORE, a treatment for lumbar disc herniation, is an ongoing task. Since HERNICORE is a drug with an unprecedented mechanism of action, our highest priority is to first of all steadily gather safety information and evidence from post-marketing surveillance studies and create an environment in which the product can be used more appropriately and with peace of mind. Although currently we are seeing decreases in the numbers of patients and surgeries due to COVID-19 infections, awareness of HERNICORE has steadily increased. We will continue to seek market penetration by approaching medical institutions through information provision activities to promote appropriate use and ensure safety and by engaging in patient awareness activities.

Launch of SI-613 (osteoarthritis treatment)

We have submitted a new drug application (NDA) for manufacturing and marketing approval in Japan for SI-613, which I mentioned above, and the NDA is currently under review. If we are able to obtain approval, we will be able to expand and upgrade our product lineup in the osteoarthritis market. Since SI-613 is a new drug in which hyaluronic acid and diclofenac (an anti-inflammatory agent) are chemically bound, we believe it will be beneficial to patients suffering from intense pain that cannot be alleviated using conventional products. Also, since the anti-inflammatory agent is administered directly into the joint cavity, the risk of systemic side effects is expected to be low. Furthermore, if we obtain approval for an NDA currently under review for use of SI-613 for the treatment of osteoarthritis at two joint sites other than the knee joint, the hip joint and ankle joint will become application sites for the first time in Japan. We consider providing patients with new treatment options our mission as a company involved in osteoarthritis treatment for many years.

The Business Development & Marketing Division will assume responsibility for SI-613, which the Research & Development Division has played a central role in developing, and work to appropriately and safely deliver it to patients in cooperation with the departments responsible for quality assurance and production.

It is essential that pharmaceutical companies develop new drugs to meet the needs of society. We believe that for Seikagaku in particular, as an R&D-driven company that does not maintain a pharmaceuticals sales force, creating an environment that enables our R&D departments to fully demonstrate their capabilities contributes to delivery of new drugs that meet patient needs as quickly as possible. The Business Development & Marketing Division aims to further enhance Seikagaku's value to society by appropriately providing products develped in this way on a global scale.

We will strengthen the profit foundation and enhance Seikagaku's value to society by opening up new markets for existing products and products in development.

Toshiyuki Okada
Executive Vice President
Head of Business Development & Marketing Division

III. Productivity improvement reforms

Topics from the first year of the mid-term management plan

Seikagaku Corporation designated "Productivity improvement reforms" as an important measure in the current mid-term management plan, and we are currently building an organization in preparation for 1) thorough cost reductions, 2) diversifying the profit model, and 3) creating an organization for maximizing resource value.

There were two major topics in the first year of the mid-term management plan. The first was recognition of a substantial impairment loss of approximately ¥13.5 billion in November 2019. As a result of a detailed examination of the business conditions and our medium- to long-term business performance trends conducted in connection with formulation of the management plan, the Company decided to recognize the lower profitability of certain property, plant and equipment related to the pharmaceuticals business as a result of the effects of National Health Insurance (NHI) drug price reductions that came out of a fundamental reform of the drug pricing system in Japan, and the sales volume of joint function improving agents falling to a level below what was expected when the capital investment was made. We think the consequent decrease in depreciation and amortization will enable us to raise the profit level in the medium term.

The second topic was the acquisition of Canada-based Dalton Chemical Laboratories, Inc. ("Dalton") as a subsidiary. I provide details on this major event, which will contribute to diversification of Seikagaku's profit model, below.

Thorough cost reductions and efficiency improvement

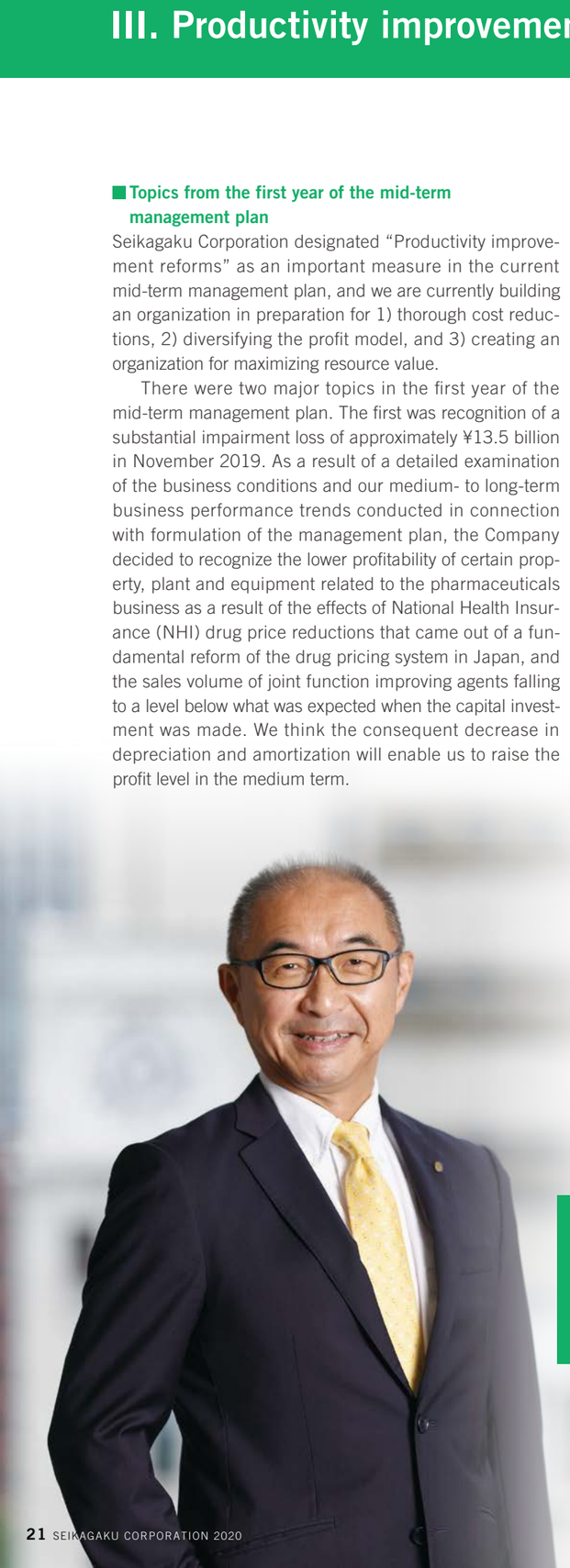
As I previously mentioned, NHI drug price reductions have had a significant impact on our mainstay products in Japan, and it is important to maintain a mindset of reducing manufacturing costs and expenses at all times. In accordance with the mid-term management plan, we have launched a project for manufacturing cost reduction that includes a review of procurement costs, and project activities are gradually producing results. Also, we will establish a stable supply structure for SI-613, a treatment for osteoarthritis we aim to launch during the period of the management plan, and develop an efficient production system for other existing drugs. Furthermore, we will work to improve overall operational efficiency and pursue cost reductions with no preconceptions.

Acquisition of Dalton

Even as we cut costs, we intend to invest capital in projects worthy of investment. As part of efforts to diversify the profit model, in March 2020, we acquired Canada-based Dalton Chemical Laboratories, Inc. as a subsidiary.

Dalton is a company with expertise in CDMO* services, including manufacturing of chemical synthetics and pharmaceutical ingredients on a contract basis. For its part, Seikagaku is a highly distinctive pharmaceutical company with strengths in extraction, refining, and prefilled syringe formulation of hyaluronic acid and chondroitin sulfate.

*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.



We will solidify the business foundation and rebuild a path to further sustained growth.

Takayuki Akita
Executive Vice President
Corporate Strategy, HR, F&A and Corporate Staff

Going forward, we will realize synergies generated through mutually complementary collaboration between the two companies. We will begin with in-house production at Dalton of chemical synthetics and investigational drugs for which Seikagaku has utilized outsourced manufacturing. Over the medium to long term, we plan to transfer to Dalton some manufacturing processes of existing Seikagaku products. Furthermore, Seikagaku and Dalton will undertake mutual improvement through exchanges of personnel and technology and pursue groupwide cost reductions. Also, introduction of Seikagaku's pharmaceutical and medical device formulation technologies and expertise to Dalton is expected to result in further expansion of Dalton's fill-finish services business.

We will undertake profitability improvement across the Seikagaku Group, including U.S.-based subsidiary Associates of Cape Cod, Inc., from the addition of Dalton's CDMO operations, a new business for the Group. We consider engaging in activities appropriate to Seikagaku's position to be the basis for achieving this improvement. We consider it vital to pursue maximization of synergies within the Group, carefully pave the way for profit growth, and take necessary measures after first making our main business the foundation for these activities.

Maximizing the value of human resources

With difficult business conditions in the domestic market continuing, acceleration of overseas expansion to support the Company's growth will become an urgent matter. To increase the pace of expansion, it will be necessary to carefully construct business strategies and implement measures to develop greater numbers of personnel who can be shifted from other tasks to execute those strategies. Accordingly, we are working to complete development of a highly transparent performance evaluation system by which employees who produce results are appropriately rewarded during the period of the current mid-term management plan. We are also considering an employee rotation system to include periodic rotation of personnel among various departments for the purpose of developing people capable of judging things from a multifaceted perspective and creating new value.

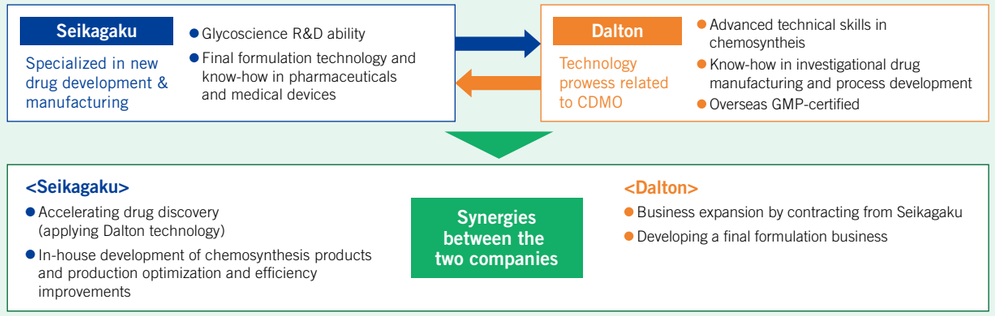
As indicated by the expression "human resources," people are an important asset to a company. We will continue to develop a workplace environment and HR systems to enable employees to realize their full potential, engage in work with enthusiasm, pride, and a sense of fulfillment, and produce results.

The period of the current mid-term management plan has been positioned as a time for solidifying Seikagaku's business foundation and rebuilding a path to further sustained growth. We believe that we must engage in groupwide reforms during this period based on the concept of overall optimization encompassing the earnings structure, R&D and production systems, HR and organizations, and IT renovation. Also, business and work styles are dramatically changing because of the impact of COVID-19 infection risk. We expect this trend to continue and intend to more proactively develop the IT environment and work environment.

I am convinced that we can build a new Seikagaku Corporation by maintaining a flexible mindset and engaging in reforms looking five to ten years into the future.

Synergistic effects of making Dalton a subsidiary

Accelerating new drug discovery and advancing production optimization and efficiency



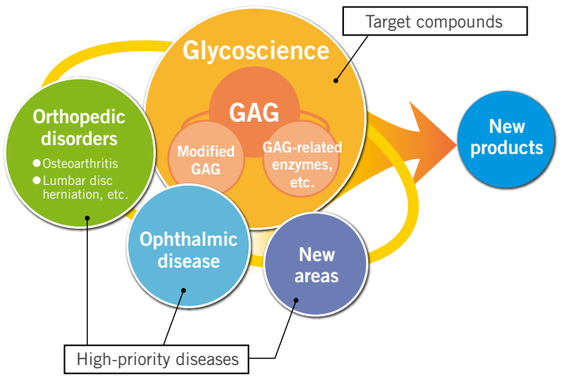
RESEARCH AND DEVELOPMENT

Seikagaku engages in research and development of innovative drugs in the 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.



*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 enter 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 combining Seikagaku's DDS technologies with drugs and technologies that other companies possess, not only low-molecular compounds, but also proteins and middle molecules such aspeptides and nucleic acids.

Seikagaku and glycoscience

Seikagaku's Management Creed states: "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 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 in 1987 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). GAG exist in living organisms as structural components of glycoconjugates. Sugar chains are known in the life sciences as the third biological chain, along with nucleic acids and proteins. They have complex chemical structures and pose characteristic difficulties in research in areas such as structural analysis, automatic synthesis, and large-scale synthesis.

Some years ago, an industry-government-academia research project focused on glycoscience was formed and its activities advanced the structural analysis and synthesizing technologies for GAG. In addition, the genes of sugar-chain synthesizing enzymes and degrading enzymes have been comprehensively identified, and our understanding of the functions of sugar chains in living organisms is advancing. This progress in glycoscience technologies is closely linked with Seikagaku's drug discovery research.

Topics

The TATENO Forum contributes to enhancement of R&D capabilities

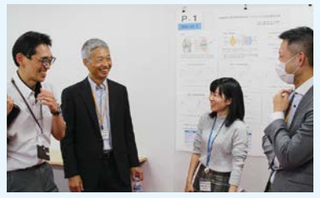
Each year in December, the Central Research Laboratory holds the TATENO Forum, an internal presentation forum for sharing research results relating to new ideas and technology creation.

There were 53 entries at the forum in fiscal 2019. In addition to young and mid-career researchers, employees from other business sites participated, actively discussing the future potential and contribution to medical needs of each research theme. Employees who submitted entries expressed their ambitious enthusiasm with comments such as, "It was a valuable opportunity to hear the views of colleagues from other departments. I want to produce results so as not to disappoint them" and "I want to try harder than ever to contribute to the creation of actual pharmaceutical products."

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 aims 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).

Employees asking insightful questions at a poster session



A cross-departmental exchange of views

RESEARCH AND DEVELOPMENT

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 March 31, 2020)

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
- Formulation Research: Exploratory formulation research based on basic physiochemical investigation of GAGs and GAG-related substances
- 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

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.

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.

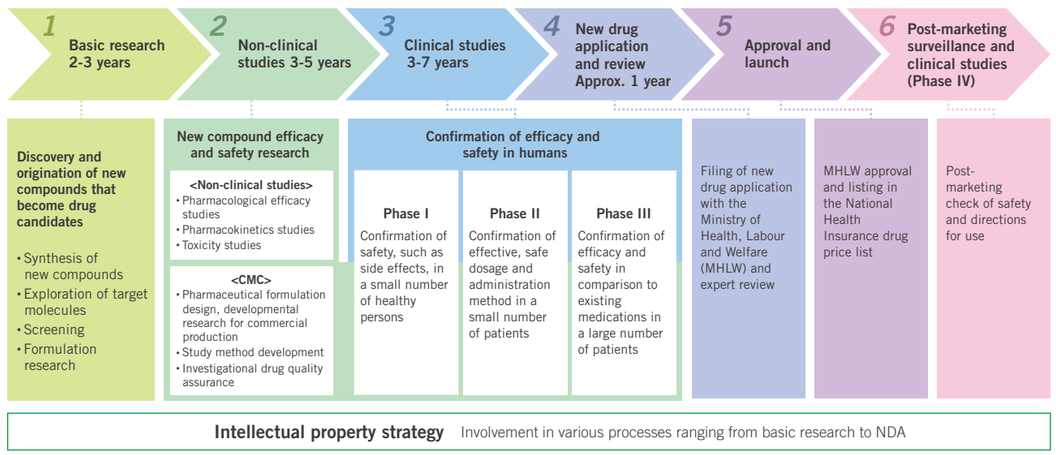
Ordinarily, more than ten years is required from discovery of a candidate substance until its approval as a new drug. Within the long, difficult new drug development process, clinical development is considered to hold the key to whether an NDA can be filed.

Clinical development

Seikagaku conducts various clinical studies in Japan and the U.S. in cooperation and collaboration with medical experts, medical institutions, and external contract research organizations (CROs) and site management organizations (SMOs). The Clinical Development Department is responsible for creating the integrated development plan (protocols); monitoring of clinical studies; planning and execution of enrollment acceleration; and data management and analysis of study results. It also communicates with the regulatory authorities in various countries and develops dossiers necessary at the time of NDA filing.

In developing protocols, the Clinical Development Department closely communicates with medical monitors and regulatory authorities, identifies requirements for NDA approval and finalizes the study design. In monitoring of clinical studies, the Department works through medical institutions to ensure the quality of studies by confirming whether they are being conducted in conformance with Good Clinical Practice (GCP) and regulatory requirements by ascertaining the condition of subjects and reviewing study data.

The Drug Research and Development Process



Ethical considerations concerning research using human biological materials

Progress in biological science has been accelerating in recent years, together with accompanying innovation of medical technologies. In particular, experiments and research using human biological materials, including genetic information, are yielding new knowledge that is expected to lead to the development of novel, highly beneficial pharmaceuticals.

In keeping with the intent of the Japanese government's guidelines on handling of human materials*, Seikagaku has established the Code of Ethics for Research Using Human Specimens to make it possible to conduct comprehensive reviews, including evaluation of ethical and scientific validity, when experiments and research using human materials are conducted. To carry out the intent of the Code of Ethics, we have established the Ethical Review Committee for Research Using Human Specimens and publish a list of committee members and minutes of committee meetings through the Japan Agency for Medical Research and Development's Ethical Review Committee eporting System of the Ministry of Health, Labour and Welfare.

*Ethical Guidelines for Human Genome and Genetic Sequencing Research and Ethical Guidelines for Medical and Health Research Involving Human Subjects

Ethical considerations in non-clinical studies

In the development of pharmaceuticals and medical devices, research activities using laboratory animals are indispensable to confirm the efficacy and safety of candidate substances, and deeply contribute to the progress and advancement of medical science.

Seikagaku strives to rigorously address ethical considerations in animal experiments and has formulated internal regulations that comply with the Act on Welfare and Management of Animals and Basic Guidelines for Animal Experimentation at Institutes under the Jurisdiction of the Ministry of Health, Labour and Welfare. Also, an ethics committee established within Seikagaku evaluates whether all animal experiments, including outsourced experiments, are planned and conducted in accordance with the 3Rs Principle*. These initiatives at Seikagaku have been evaluated as conformant with the 3Rs Principle by the Japan Health Sciences Foundation's Center for Accreditation of Laboratory Animal Care and Use, a third-party organization.

*3Rs Principle: Methods that avoid or replace the use of animals (Replacement), methods that minimize the number of animals used per experiment (Reduction), and methods that minimize animal suffering (Refinement)

Development Pipeline

[Pharmaceuticals]

(As of September 30, 2020)

Development code, substance name		Indication	Developed in	Phase I	Phase II	Phase III	NDA
SI-6603	Condoliase	Lumbar disc herniation	USA				
SI-613	Hyaluronic Acid-Diclofenac Conjugates	Osteoarthritis	Japan				
		Knee osteoarthritis	USA				
SI-613-ETP	Hyaluronic Acid-Diclofenac Conjugates	Enthesopathy	Japan		Late-stage Phase II		
SI-614	Modified Hyaluronate	Dry eye	USA			Phase II/III	
SI-722	Steroid conjugated with chondroitin sulfate	Interstitial cystitis and bladder pain syndrome	USA	Phase I/II			

[Medical Devices]

Development code, substance name		Description	Developed in	Pilot study	Pivotal study	NDA
SI-449	Cross-linked Chondroitin Sulfate	Adhesion barrier	Japan			

<Impact of COVID-19 Infections>

Delays have occurred in the progress of an additional Phase III clinical study of SI-6603 and Phase I/II clinical studies of SI-722 underway in the U.S. due to discontinuation of clinical studies at some medical institutions and an increase in the number of subjects postponing hospital visits due to the spread of the COVID-19 infection. We are taking measures to enroll subjects and proceeding with implementation of clinical trials while placing the highest priority on the situation at medical institutions and prevention of infection of patients and medical personnel. We are also are carefully moving ahead with preparations for the start of subject enrollment for a pivotal study of SI-449 in Japan while placing the highest priority on preventing infection of patients and medical personnel.

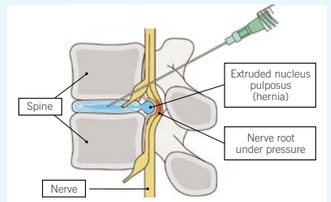
Overview of Development Pipeline

SI-6603 (treatment for lumbar disc herniation)

SI-6603, which contains condoliase as its active pharmaceutical ingredient, is a treatment for lumbar disc herniation. Since it is a treatment directly injected into the intervertebral disc, it does not require a general anesthesia and is 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.

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.

In the U.S., although the expected pharmacological effect was demonstrated in a Phase III clinical study, the study did not meet its primary endpoint of improvement in leg pain. Although Seikagaku has been conducting an additional Phase III clinical study since February 2018 in response to this result, since we have applied stringent subject enrollment criteria to increase the probability of success, and it is taking time to set up clinical trial sites, in November 2019 we decided to extend the timing of completion of the study by two years beyond the original plan. (Follow-up observations are scheduled for completion in November 2022.)



Administration of SI-6603

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. Since SI-613 combines the pain relief and anti-inflammatory effect of a diclofenac formulation designed using the drug delivery systems for sustained release with the joint function improving effect of hyaluronic acid, it is expected to provide prompt and long-lasting relief of the pain and inflammation associated with osteoarthritis and enthesopathy.

In Japan, in January 2020 Seikagaku submitted a new drug application (NDA) for manufacturing and marketing approval relating to the efficacy and effectiveness of SI-613 in the treatment of osteoarthritis (knee joint, hip joint, ankle joint) based on the results of three Phase III clinical studies, and the NDA is currently under review.

In the U.S., a Phase II clinical study targeting osteoarthritis has been completed, and we are considering a Phase III study while proceeding with selection of a sales partner. In April 2020, Seikagaku entered into an agreement with Eisai Co., Ltd. concerning co-development of SI-613 and a marketing alliance in China, and we are formulating a clinical trial plan in preparation for future development.

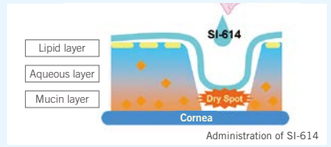
Data analysis of a late-stage Phase II clinical study in Japan of SI-613-ETP for the treatment of enthesopathy has been completed, and we are considering the next clinical study together with co-development and marketing partner Ono Pharmaceutical Co., Ltd.

Administration of SI-613

SI-614 (treatment for dry eye)

SI-614, an ophthalmic solution, is a modified hyaluronate produced using Seikagaku's proprietary technology. Ocular instillation of SI-614 is expected to protect the ocular surface and promote corneal wound healing.

A Phase II/III clinical study was completed in January 2015, and Seikagaku is currently proceeding with selection of a co-development and sales partner.

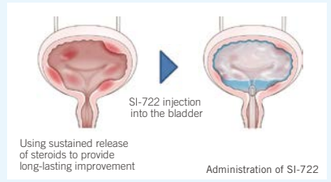


Administration of SI-614

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 long-lasting improvement in the conditions of frequent urination and bladder pain by releasing a steroid with an anti-inflammatory effect.

A Phase I clinical study of SI-722 in the U.S. was completed, and Phase I/II clinical studies were initiated in November 2019. This study will evaluate SI-722 for safety, tolerability, and pharmacokinetics and include an explorative evaluation of its effectiveness.

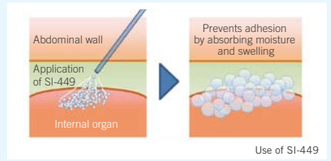


Administration of SI-722

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. Since it is a powdered formulation, it adheres well to uneven tissue surfaces. It is thought to offer excellent utility in laparoscopic surgery, an increasingly common surgical procedure.

Since positive results were confirmed in a pilot study of SI-449 initiated in May 2018, a pivotal study to confirm adhesion prevention effect, safety, and operability was initiated in May 2020.



Use of SI-449

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* 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 are working to improve production efficiency through periodic checking and improvement of manufacturing processes.

We will continue to pursue continuous improvement and focus on the manufacture and supply of high-quality products that comply with global standards.

Ensuring a stable supply of products

Providing a stable supply of products is an important mission of a pharmaceutical company. Seikagaku prepares against major disasters and other risks by diversifying raw materials suppliers and maintaining appropriate inventory levels. At the Takahagi Plant, which is responsible for manufacturing the finished products, we have introduced a quake-absorbing structure that reduces shaking for the main production buildings when an earthquake occurs. Through these measures, we have put in place a system capable of stable, reliable product production even in an emergency.

Furthermore, to cope with product supply risk from distribution network disruption following a disaster, we maintain a certain level of product inventory and have product warehouses in two separate locations: within the Takahagi Plant in Takahagi City, Ibaraki Prefecture in the Kanto region and in Hirakata City, Osaka in the Kansai region.

Environmental impact reduction initiatives

Seikagaku is keenly aware of the importance of protecting the global environment. We observe environment-related laws and regulations and voluntarily engage in environmentally friendly business activities. At our plants, in the treatment of water used in pharmaceutical production, we have introduced electro-deionization facilities that use no hydrochloric acid or caustic soda and, in wastewater treatment, we have adopted a system that uses ozone treatment and the activated sludge process.

Also, with the objective of reducing CO_2 emissions, we have established the Energy Conservation Promotion Committee and are managing energy use, and we are implementing improvement measures as well as providing education and training on energy conservation to achieve reduction targets set at each business site. Furthermore, the Committee is putting in place a framework for increasing efficiency at the Group level by coordinating energy use and CO_2 emissions results and reduction measures for each fiscal year, reporting to the Management Committee, and deliberating on related matters. As a result, we have achieved our average energy reduction rate targets for the five years up to fiscal 2019.

*CDMO:
Contract Development and Manufacturing Organization
A company that provides comprehensive manufacturing and development services to pharmaceutical companies, including drug manufacturing on a contract basis and manufacturing of investigational drugs and optimization of manufacturing conditions at the drug development stage.

Overview of Production Sites

Takahagi Plant (Takahagi City, Ibaraki Prefecture)

The Takahagi Plant, located in northern Ibaraki Prefecture, is responsible for manufacturing finished pharmaceuticals and medical devices, including the joint function improvement agents that are Seikagaku's mainstay products. When the plant opened in 1975, it had 28 employees. Since the launch of hyaluronic acid formulations in 1987, it has steadily expanded production scale as a manufacturing plant that specializes in injectable formulations. Today, the Takahagi Plant occupies a site of approximately 86,000 square meters and has five production buildings and some 300 employees.

The Takahagi Plant is one of the world's largest manufacturing sites for hyaluronic acid pre-filled syringe formulations*, producing more than 25 million units per year for the Japanese and overseas markets. 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 and that assure sterility of the products.

*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, opened in 1947 and is Seikagaku's most experienced plant. The plant 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 some of the manufacturing processes for condoliase, the active pharmaceutical ingredient of HERNICORE, a treatment for lumbar disc herniation. The Plant is currently preparing to start up new bulk condoliase manufacturing facilities to further strengthen the production scale.

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 52.

Topics

Acquisition of new manufacturing and analysis technologies

Seikagaku is switching from outsourced manufacturing to in-house production of condoliase, the active pharmaceutical ingredient of HERNICORE, a treatment for lumbar disc herniation. The Kurihama Plant, which is responsible for the changeover, has experience in manufacturing hyaluronic acid and other pharmaceutical raw materials, mainly by extracting and purificating GAG from natural substances. However, since condoliase is manufactured using microbial culture technology and an enzyme (a form of protein) separation and refining technology, its manufacture represented a new challenge for Seikagaku. The changeover process began with installation of facilities at the manufacturing plant and, following a battery of repeated tests conducted in close cooperation with involved departments, is now at the stage of process validation, which is final confirmation work performed before actual production. The Kurihama Plant will now aim for an early start of production and further perfect the newly acquired manufacturing and analysis technologies to enable delivery of high-quality products to patients.

Members of the project

MARKETING

Seikagaku has a unique 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

Seikagaku manufactures pharmaceuticals and medical devices with, as their main ingredient, glycosaminoglycans (GAG) such as hyaluronic acid, which are the structural components of glycoconjugates, and also products based on enzymes that act on GAG. To deliver these products to patients globally, Seikagaku forms partnerships with pharmaceutical companies that have expertise in each market, including Japan.

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, from glass to plastic. Through these efforts, we are adding value to our products.

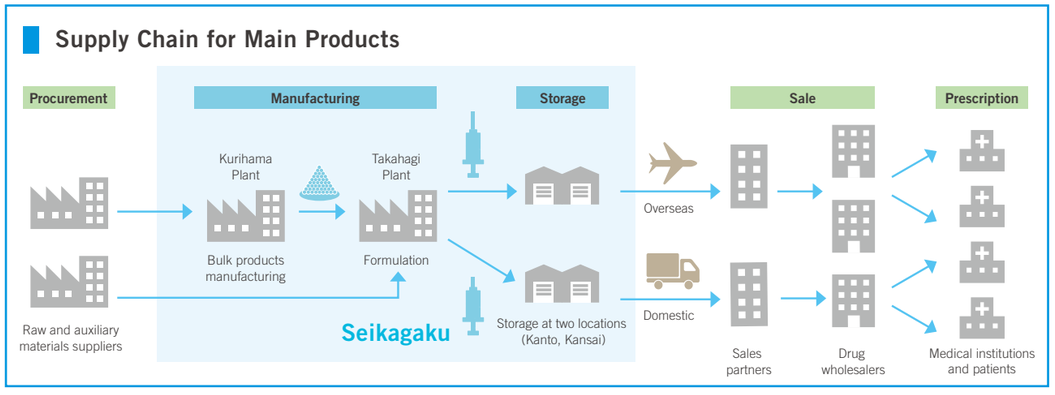
Furthermore, we have been accelerating overseas business expansion in recent years. We are working to increase sales in countries where we already do business, and to meet global medical needs, we are implementing a plan to introduce existing products and products in development into new markets.

Bulk products

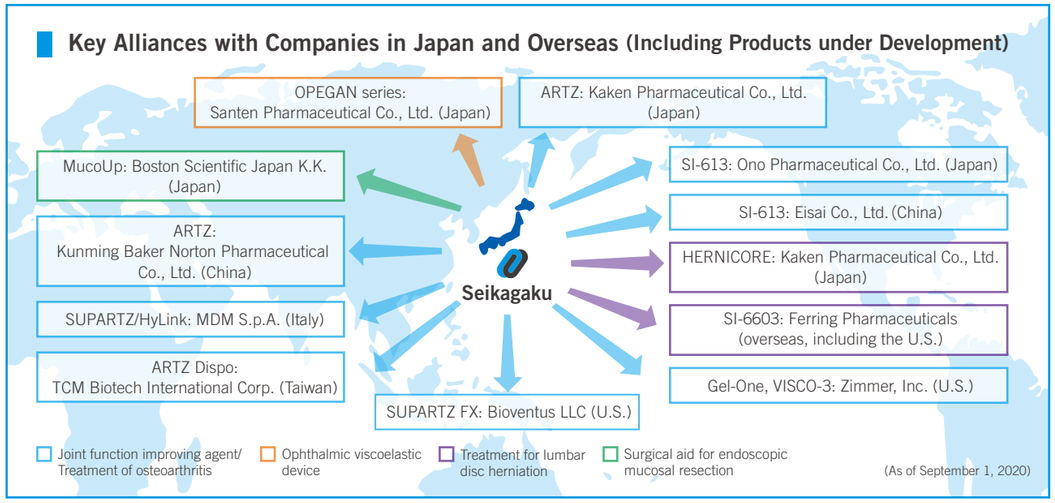
Seikagaku's business can be traced back to 1950 when it became the first company in the world to successfully produce chondroitin sulfate on a commercial scale. The key to success was its unique extraction and purification technologies. With these technologies, Seikagaku manufactures high-purity and 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.

Supply Chain for Main Products



Key Alliances with Companies in Japan and Overseas (Including Products under Development)



Endotoxin-detecting reagents (LAL business)

The endotoxin-detecting reagents that Seikagaku provides are mainly used in quality control of pharmaceutical and medical device manufacturing processes and water quality control of dialysate used in artificial dialysis.

Seikagaku is engaged in the development of the LAL business in Japan, selling endotoxin-detecting reagents and related devices mainly to pharmaceutical companies that manufacture injectable formulations, while 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.

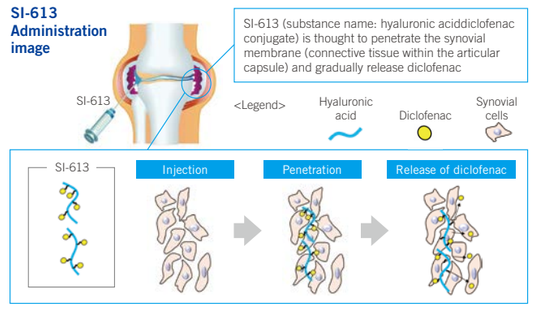
Topics

Conclusion of an agreement with Eisai on a co-development and a marketing alliance in China for SI-613

In April 2020, Seikagaku concluded an agreement with Eisai Co., Ltd. concerning co-development and a marketing alliance in China for SI-613, an osteoarthritis treatment. On the basis of this agreement, the two companies will jointly develop SI-613 for the treatment of knee osteoarthritis, and after approval has been obtained, Seikagaku will supply the product to Eisai, and Eisai will be responsible for distribution. The number of symptomatic patients in China suffering from knee osteoarthritis, a form of osteoarthritis that occurs with particularly high frequency, is said to be approximately 47 million* (some six times the number in Japan) it is anticipated that the number will continue to increase as the population ages. Currently, we are formulating a plan for clinical studies in China in cooperation with Eisai, which has a wealth of knowledge and networks cultivated in its China operations.

Seikagaku has submitted a new drug application for manufacturing and marketing approval of SI-613 in Japan, and a Phase II clinical study has been completed in the U.S. We will now aim for further multinational expansion by proceeding with development in China.

SI-613 Administration image



*For the estimated data regarding the number of patients with knee osteoarthritis
- Data of morbidity prevalence rate - The Prevalence of Symptomatic Knee Osteoarthritis in China, ARTHRITIS & RHEUMATOLOGY(2016)
- Estimated data calculated from United Nations World Population Estimates - World Population Prospects, URL http://www.un.org/en/development/desa/population/

QUALITY COMPLIANCE

Seikagaku's mission is to provide society with a continuous supply of 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 makes maximum effort to ensure quality at every stage, from R&D to post-marketing by complying with the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices ("PMD Act") and a collection of regulations and guidelines called GxP.* In Japan, as a marketing authorization holder, we have developed a system with three key roles (general marketing compliance officer, quality assurance supervisor, and safety management supervisor) and implement appropriate quality management and pharmacovigilance operations.

To continue to reliably provide pharmaceuticals and medical devices required by patients around the world, we will strive to maintain and enhance quality assurance and compliance systems in accordance with global standards.

*GxP is an abbreviation for Good XXX Practice, a collective term for standards established to ensure the efficacy, safety, and quality of pharmaceuticals and medical devices from the R&D stage to post-marketing. (See the diagram to the right.)

Quality management system based on global standards

To provide a stable supply of high-quality pharmaceuticals and medical devices, according to our Quality Policy, we have developed a quality management system that ensures the reliability of our products worldwide. At the development stage, we ensure reliability under Good Laboratory Practice (GLP) and Good Clinical Practice (GCP). To guarantee quality assurance in accordance with legal and regulatory requirements after product launch, 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.

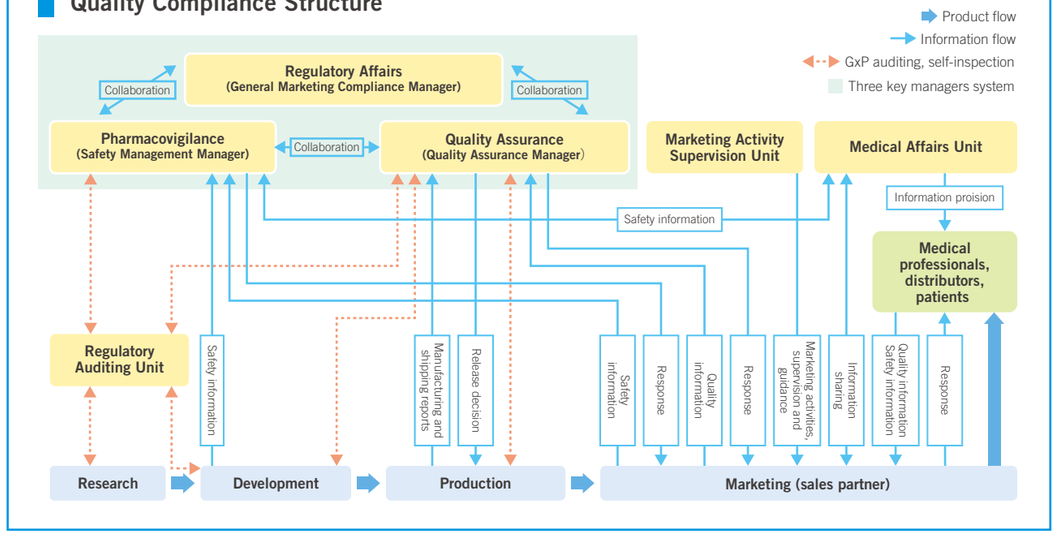
ISO 13485 is an international standard for quality management systems established by the International Organization for Standardization (ISO) that prescribes requirements concerning the design, development, and manufacturing of medical devices. In Japan, ISO 13485 has been adopted as an ordinance on standards for manufacturing control and quality control of medical devices and in vitro diagnostics.

Laws and Regulations Governing Pharmaceuticals and Medical Devices

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

- PMD (Pharmaceutical and Medical Device) 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

Quality Compliance Structure



Safety management

Sometimes side effects not observed in the development stage come to light after the launch of a new drug. 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 drugs prescribed at medical facilities. Through these activities, we prevent the expansion of side effects and promote safety assurance and appropriate use of new drugs.

Medical information collection and provision activities

Seikagaku has established the Medical Affairs Unit, which engages in activities to provide current scientific knowledge to external professionals independently from the marketing division. As scientific experts with sufficient ethical perspective, the MSL Unit contributes to medical progress by creating and disseminating medical evidence relating to disease information and products in the fields in which Seikagaku focuses, such as orthopedic disorders and ophthalmic diseases.

Topics

Support for product value optimization and long-term post-marketing drug development

The Medical Affairs Unit will be engaged in activities to provide appropriate information to prescribing physicians through the dissemination of unbiased medical and scientific information. Specifically, it satisfies medical needs by appropriately gathering information on unmet medical needs from medical experts at Advisory Board meetings and other forums, by planning and conducting independent research and joint research based on those needs and, ultimately, by disseminating information via conference presentations and research papers.

The true value of ethical pharmaceuticals is provided by adding information to manufactured products. The Medical Affairs Unit will continue to support optimization of product value and long-term post-marketing drug development by continuing to gather information on unmet medical needs from physicians and disseminate valuable information.

Deliberation by the Advisory Board

HUMAN RESOURCES

Seikagaku aims to develop self-driven and self-disciplined employees who can contribute to sustainable growth.

Development of human resources

Seikagaku Corporation considers human resources to be an important corporate asset and seeks people who understand and put into practice our core values “creativity,” “fairness,” and "dreams and passion” and are capable of self-growth while fulfilling their roles with a sense of responsibility.

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 of individuals through a combination of systematic education in various training programs, personnel training in the workplace through day-to-day work, and job rotation.

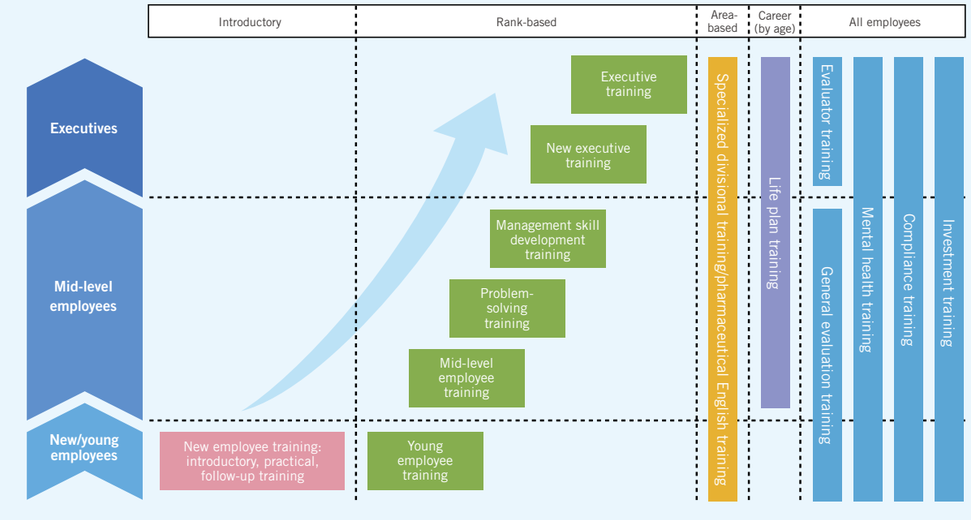
In addition, to develop the human resources required by each division and department, we conduct age-specific and level-specific training for everyone from rank-and-file employees to executives.

Work-life balance

To help its employees achieve a good work-life balance, Seikagaku has introduced flextime at all of its business sites except for a few production operations and established a weekly “no overtime day” to encourage employees to leave work at the normal finishing time. To help employees balance their personal lives with their work, Seikagaku encourages them to develop their own workstyles. For example, we now have a reduced-working-hours system to help employees with childcare and nursing care duties, 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, 2020 (fiscal 2019), employees used an average of 78.2% of their paid leave. In the period from fiscal 2007 to fiscal 2019, 100% of staff who left work for childcare reasons returned to work. The number of male employees taking childcare leave has also increased in recent years. Seikagaku will consider new ways to meet workstyle needs as one way to improve working environments.

Furthermore, staff assignments consider the quality and quantity of work, improvement of the workplace environment, and correction of long working hours to help create employee-friendly workplaces.

Training Systems



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 2016, we launched a project to promote women’s free advancement in the workplace and to raise internal awareness. Since then, spearheaded by women, we have worked to improve internal systems, based on interviews with all female employees, and held workshops to foster a culture that supports female advancement. As of March 31, 2020, the ratio of female managers was 14.5%, a sharp increase from 7.9% three years earlier.

In 2020, we changed the project into a diversity and inclusion project to further ensure that the contributions and successes of diverse employees are the driver of Seikagaku’s sustained growth.

COVID-19 Infection Countermeasures

At Seikagaku, we have taken the following infection prevention measures that give the highest priority to our employees, their families, and local community residents and have implemented the following COVID-19 infection response to ensure continuity of business operations. We are appropriately and promptly reviewing these arrangements in accordance with the infection situation and other considerations.

<Thorough infection prevention measures>

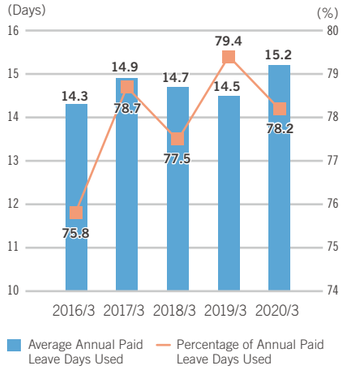
- We periodically circulate information internally about key points and rules concerning infection prevention.
- We recommend working from home for workplaces and employees where it is practicable. We have set a target for the percentage of employees working on-site and are rigorously implementing control measures.
- To improve the working environment for work from home, we are introducing mechanisms for accessing internal systems and introducing an online meeting system, having first prioritized information security measures.
- We are implementing initiatives to realize flexible work styles for employees through changes in commuting methods and expanded operation of a flextime work system.
- In addition to placement of hand sanitizer dispensers and installation of airborne droplet prevention boards, we are taking measures to reduce contact among employees in the workplace to the extent possible as internal infection prevention measures.

<Response to ensure continuity of business operations>

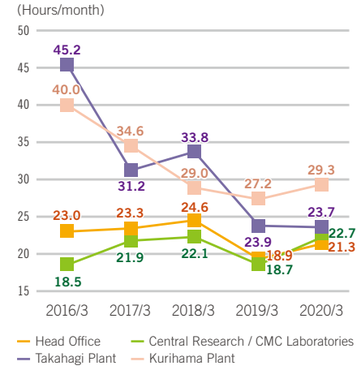
- To fulfill our responsibility as a pharmaceutical company to supply pharmaceutical products and medical devices while placing the highest priority on infection prevention, we are working to avoid disruption of the manufacturing and sale of products and compliance with laws, ordinances, and regulations.
- To continue new drug development, we will implement a prioritized research plan and conduct clinical studies in accordance with the wishes of trial sites while giving sufficient consideration to preventing infection of participating patients and medical personnel.
- As a business risk management initiative, in March 2020 we established an emergency headquarters for the purpose of ensuring continuity of business operations and rigorously practicing infection prevention measures and are developing a system to efficiently devise measures and respond to risks.

Note: This information is current as of September 30, 2020.

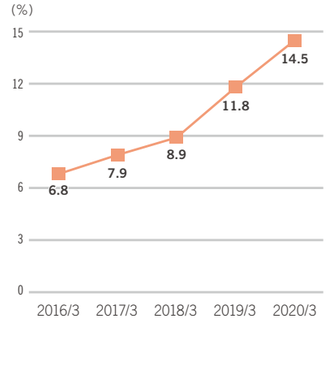
Use of Paid Leave



Average Overtime Hours by Business Site



Executive Positions Held by Women



*The figures provided on this page are all on a non-consolidated basis.

CORPORATE GOVERNANCE

Members of the Board (as of June 19, 2020)

President & CEO *
Ken Mizutani

Term of office as Director:
30 years

Number of the Company's shares owned:
452,809 shares

Executive Vice President
Business Development & Marketing
Toshiyuki Okada

Term of office as Director:
3 years

Number of the Company's shares owned:
7,490 shares

Executive Vice President
Research & Development
Yosuke Funakoshi

Term of office as Director:
2 years

Number of the Company's shares owned:
8,090 shares

Executive Vice President
Corporate Strategy, HR, F&A and Corporate Staff
Takayuki Akita

Term of office as Director:
2 years

Number of the Company's shares owned:
4,690 shares

Outside Member of the Board
Eiji Katayama

Term of office as Director:
16 years

Number of the Company's shares owned:
37,100 shares

Outside Member of the Board
Mio Minaki

Term of office as Director:
1 year

Number of the Company's shares owned:
—

Audit & Supervisory Board Member
Toru Takeda

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

Number of the Company's shares owned:
2,200 shares

Audit & Supervisory Board Member
Shigeru Kawahara

Term of office as Audit & Supervisory Board Member:
3 years

Number of the Company's shares owned:
5,300 shares

Outside Audit & Supervisory Board Member
Mie Fujimoto

Term of office as Audit & Supervisory Board Member:
5 years

Number of the Company's shares owned:
1,400 shares

Outside Audit & Supervisory Board Member
Shinkichi Matsuo

Term of office as Audit & Supervisory Board Member:
1 year

Number of the Company's shares owned:
—

Outside Audit & Supervisory Board Member
Takayuki Maruyama
(New election)

Term of office as Audit & Supervisory Board Member:
—

Number of the Company's shares owned:
—

Quality Compliance & Medical Affair Executive Vice President
Yuji Shimojima

Head of Corporate Staff
Executive Vice President
Mikako Torii

Head of Takahagi Plant
Head of Production
Executive Vice President
Masayuki Ito

*Ken Mizutani concurrently serves as an executive officer.
Notes: 1. Terms of office are as of June 19, 2020.
2. Number of the Company's shares owned is as of March 31, 2020.

Basic policy of corporate governance

Seikagaku Corporation views corporate governance as a core area of management priority, and endeavors to gather information accurately and adequately, speed up decision-making, and strengthen the supervisory function of business execution. We are profoundly aware of our social mission and responsibilities as a pharmaceutical company, and are committed to always earning the confidence of stakeholders, including our shareholders. In addition to establishing internal control systems, such as for compliance and risk management, we are enhancing our corporate governance through mutual collaboration among departments within the Company in order to create a management environment that meets the expectations of society.

Overview of the corporate governance system and reasons for adopting the system

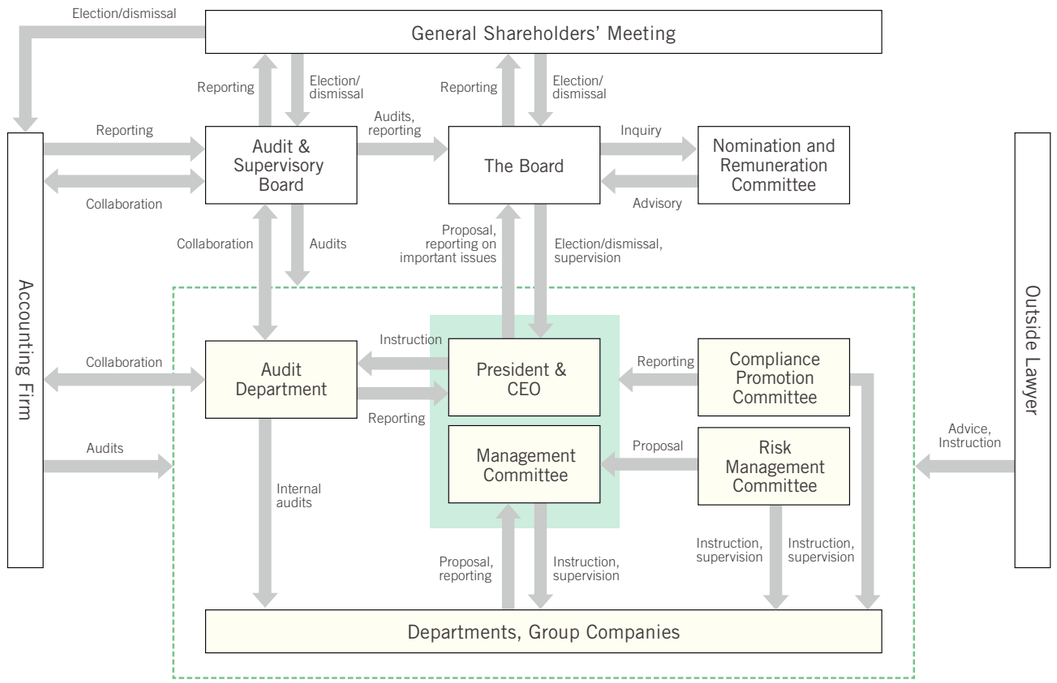
The Company has adopted a Company with an Audit & Supervisory Board governance system and established a General Shareholders' Meeting, Board of Directors, and Audit & Supervisory Board as company institutions. In light of the Company's size and highly specialized business operations as a pharmaceutical company, it has determined that the most effective and appropriate form of corporate governance for the Company is for the Board of Directors, which includes outside directors, to oversee the performance of duties of corporate officers engaged in business execution and for the Audit & Supervisory Board to perform auditing and oversight in cooperation with the accounting auditor. An overview of the Company's corporate governance system follows.

Concrete approach and measures for corporate governance

The Board

- The Board holds regular monthly meetings to make decisions on tasks stipulated in laws, the Articles of Incorporation and rules for the Board, such as basic management policy, mid-term management plan, annual management plan, and election of executive vice presidents. The Board decides on important business, and supervises the performance of business operations. If necessary, additional meetings of the Board are convened.
- 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 Board comprises four full-time and two outside members. We enhance management oversight from an independent standpoint by appointing outside members of the Board to one-third of the Board seats.
- The outside members of the Board are responsible for oversight from an objective standpoint, a perspective that

Corporate Governance Structure



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.

- All two outside members of the Board are reported to the Tokyo Stock Exchange, Inc. as independent officers.
- To enable sufficient deliberation at Board meetings, as a rule materials on agenda items and reporting matters are distributed to the Board members at least three days before meetings to provide time to review the materials.
- The Board consults with the Nomination and Remuneration Committee, which consists of the president & CEO and all outside members of the Board, in determining matters concerning compensation and candidates for members of the Board, and makes decisions based on the advice received. By a resolution of the Board of Directors, the amount of compensation for directors (excluding restricted stock compensation) is determined at the discretion of the Nomination and Remuneration Committee.

Analysis and evaluation of the effectiveness of the Board of Directors

- A meeting of outside officers, comprising the outside directors 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 to the Board the results of evaluation and areas for improvement.
- The evaluation for fiscal 2019 found that the Board of Directors functions properly in deciding important matters and overseeing business execution and that its effectiveness is sufficiently ensured. It also found that improvements have been made in areas such as making reports on business execution easier to understand and creating opportunities for sharing important management matters with the outside officers and seeking their opinions.
- Proposals included continued improvement of Board meeting materials and clarification of criteria for agenda items and proposals, and the Board will undertake improvement in these areas.

Audit framework

- The Audit & Supervisory Board comprises five members, two full-time and three outside members, and each member audits the Board members' execution of duties.
- Out of the five members, each full-time and outside member has enough knowledge of finance and accounting.
- The outside members suitably perform supervision of 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.
- The main matters for consideration by the Audit & Supervisory Board include formulation of the audit policy and audit plan, development of the internal control system and confirmation of its status of operation, preparation of audit reports, and the reasonableness of the accounting auditor's methods and results.
- Audit & Supervisory Board members attend meetings of the Board of Directors, interview directors in charge and corporate officers of subsidiaries in accordance with an annual plan, and exchange views with the president & CEO. They also have periodic meetings with the accounting auditor and Audit Department and receive audit reports, audit results, and other reports.

Accounting audit and Internal audit frame work

- Seikagaku has selected Deloitte Touche Tohmatsu LLC as the accounting auditor following comprehensive evaluation of its auditing accomplishments, independence, quality control system, and other factors.
- The Corporate Audit Department, consisting of two employees, conducts audits for the purpose of assessing and verifying the legality and appropriateness of the Seikagaku Group's operations.

Coordination between Audit & Supervisory Board members, accounting auditors, and internal audits

- The Audit & Supervisory Board members and the Corporate Audit Department met 17 times during fiscal 2019 to review audit results related to internal controls at each internal division, and share information and views on the audit plan and the status of audits conducted by the Corporate Audit Department. They also aim to reach a mutual understanding through spontaneous communications.
- Regarding the state of coordination between the Audit & Supervisory Board members and the accounting auditors, information exchange was provided for on 10 occasions during fiscal 2019, and the year's plan for the auditing firm and the results of the financial audit were received at a hearing where views on these matters were also exchanged.
- The Corporate Audit Department cooperates with the accounting auditors to share information and exchange views on audit plans concerning internal controls, audit implementation status and audit results for ensuring the reliability of the Company's financial reports.

Business operations

- Seikagaku operates an executive vice president system for enhancing the corporate governance. Under this system, executive functions are separated from the Board, the functions of which are limited to decision-making and the supervision of business operations. Seikagaku endeavors to build up an internal system, which is quickly able to respond to changes in the management environment, by improving the flexibility and efficiency of executive functions, expanding the executive vice president system, and promoting the transfer of authority.
- Seikagaku holds weekly Management Committee meetings. The Committee, composed of full-time members of the Board and executive vice presidents, confers and decides agendas of executive functions they have been tasked for implementation by the Board, based on the basic policy of the Board.

Compliance/risk management

- In addition to the social ethics code, in order to comply with strict laws and regulations of the pharmaceutical industry, Seikagaku has established a compliance program (including the SKK Group Compliance Code of Conduct) based on the Creed and the Guidelines for Our Activities as defined in our Core Values. The Seikagaku Compliance Program Handbook is compiled and distributed to increase the awareness and understanding of employees.
- The Compliance Committee is chaired by the president & CEO and shares the same members as the Management Committee. There are also various programs to promote compliance on a company-wide basis. And Seikagaku has implemented various measures to enhance effectiveness.
- To appropriately manage business risks and take risk prevention measures, Seikagaku has established a Risk Management Committee, chaired by a Board member in charge of administration and comprising the executive vice presidents in charge of various departments.
- Seikagaku controls subsidiaries adequately by stipulating the rules for regularly reporting important events, such as compliance and risk status, in addition to financial condition.
- Seikagaku ensures that management decision and daily business execution are in compliance with laws and regulations by receiving advice and instructions from outside lawyers.

Outside members of the Board and outside Audit & Supervisory Board members

Interests including those having a personal relationship, capital relationship, or transactional or other business relationship with the Company

- Concerning relationships between our company and another company in which the same person serves, or has served, as an outside member of the Board or an outside Audit & Supervisory Board member, there are no interests that would be affected by a personal relationship, a capital relationship, a business relationship, or performance of other work duties.

Functions and roles carried out in corporate governance

- The outside members of the Board oversee management and contribute to strengthening of the Company's corporate governance system by providing advice and recommendations from an objective standpoint, which is based on expert knowledge and insights into corporate management and incorporates the common interests of shareholders.
- The outside Audit & Supervisory Board members appropriately fulfill their role of overseeing the execution of duties by Board members by striving to gather information and expressing their views from an objective standpoint, which is based on expert knowledge and insights into corporate management and incorporates the common interests of shareholders.

Main activities of the outside members of the Board and the outside Audit & Supervisory Board members (fiscal year ended March 31, 2020)

Officer category	Last/First name	Independent officer	Board meetings	Audit & Supervisory Board meetings
Outside member of the Board	Eiji Katayama	○	Attended 13 of 13 meetings	—
	Mio Minaki	○	Attended 10 of 10 meetings	—
Outside Audit & Supervisory Board members	Yoshihito Shibata	○	Attended 12 of 13 meetings	Attended 14 of 14 meetings
	Mie Fujimoto	○	Attended 13 of 13 meetings	Attended 14 of 14 meetings
	Shinkichi Matsuo	○	Attended 10 of 10 meetings	Attended 10 of 10 meetings

Notes: 1. The attendance figure for Ms. Mio Minaki indicates her attendance at meetings held after her appointment in June 2019.
2. Mr. Yoshihito Shibata retired at the conclusion of the 74th Ordinary General Shareholder's Meeting, held on June 19, 2020.
3. The attendance figure for Mr. Shinkichi Matsuo indicates his attendance at meetings held after his appointment in June 2019.

Compensation for corporate officers

Basic policy

The Company's basic policy on compensation for directors (excluding outside directors) is to contribute to sustained earnings improvement by increasing incentives for directors to meet the expectations of shareholders. Compensation consists of basic compensation that reflects consideration of the balance between the going rate, management performance, and employee salaries and, for directors other than outside directors, earnings-linked compensation and performance-linked compensation, which serve as short-term incentives, and restricted stock compensation, which serves as a long-term incentive.

Short-term incentives

<Earnings-linked compensation>

Earnings-linked compensation is determined through assessment in accordance with the level of profits in the previous fiscal year using SKK EBITDA, a numerical target in the mid-term management plan (fiscal 2019 to fiscal 2021), as the profit indicator. SKK EBITDA is Seikagaku's own profit indicator consisting of operating income plus depreciation expense and royalty income. The Company has selected SKK EBITDA because it considers it appropriate as an indicator that creates a short-term incentive for achievement of rapid solidification of the profit foundation, an objective set forth in the mid-term management plan.

<Performance-linked 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.

Long-term incentive

<Restricted stock compensation>

Restricted stock compensation, which involves the granting each year of common shares of the Company for which transfer is restricted until retirement, is determined by multiplying the basic compensation of each director (excluding outside directors) by a fixed rate for each position. The purpose is to provide an incentive to pursue sustained enhancement of the Company's corporate value and promote further sharing of value with the shareholders by promoting long-term, stable shareholding. (Restricted stock compensation was introduced by a resolution of the 73rd Ordinary General Shareholders' Meeting held on June 19, 2019.)

Compensation for outside directors and Audit & Supervisory Board members

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

Method of determining compensation for corporate officers

By a resolution of the Board of Directors, compensation for each director (the amount of basic compensation as well as the amount of earnings-linked compensation and the amount of performance-linked compensation for each director [excluding outside directors]), within the maximum amount approved by the General Shareholders' Meeting, is determined at the discretion of the Nomination and Remuneration Committee, comprising the president & CEO and all of the outside directors. The amount of remuneration rights pertaining to the restricted stock compensation system is determined by a resolution of the Board of Directors following deliberation of the time of payment, allocation policy, and other matters by the Nomination and Remuneration Committee.

The balance between the going rate, management performance, and employee salaries is taken into consideration in determining compensation for directors. Compensation for Audit & Supervisory Board members is determined following discussion among them, within the maximum amount of compensation approved by the General Shareholders' Meeting.

Total amount of compensation for each category of officer, total amount by type of compensation, and the number of relevant officers (fiscal year ended March 31, 2020)

Officer category	Total compensation (Millions of yen)	Total by type of compensation (Millions of yen)			Number of officers
		Basic compensation	Earnings-linked and performance-linked compensation	Stock compensation	
Members of the Board*	208	184	14	8	4
Outside officers	25	25	—	—	3
Audit & Supervisory Board members*	45	45	—	—	2
Outside Audit & Supervisory Board members	22	22	—	—	4
Total	300	276	14	8	13

*Excluding outside officers and outside Audit & Supervisory Board members

Notes: 1. Based on the status at the time of adjournment of the 73rd Ordinary General Shareholders' Meeting held on June 19, 2019, one retired outside member of the Board and one retired outside Audit & Supervisory Board member are 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. 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 Board member proportion shall be no more than ¥50 million per year). Also, the amount of compensation for separately granting restricted stock to directors (excluding outside directors) was resolved at the 73rd Ordinary General Shareholders' Meeting held on June 19, 2019 to be no more than ¥50 million per year.
4. 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.

Messages from an outside member of the Board and outside Audit & Supervisory Board member

Eiji Katayama
Outside Member of the Board

Enhancement of the governance system that supports continuous new drug development

It is my assessment that Seikagaku's corporate governance has been appropriately reformed in conjunction with the enactment and revision of the Corporate Governance Code in recent years. In practical terms, the Company distributes materials and provides explanations of important matters in advance of the Board, and I feel that the quality of the materials has improved greatly. Also, the Company has instituted a discretionary Nomination and Remuneration Committee, and the design and decision process of Board members' remuneration have notably increased in transparency. Furthermore, the Audit & Supervisory Board and the outside directors hold gatherings for discussion with the Board members from time to time, which provide a useful opportunity for learning about the current situation at divisions and departments and the views and personalities of the Board members and executives. I feel that the ability to engage in comparatively frank exchanges of opinion at such forums is extremely beneficial for outside directors. I consider further deepening of discussion within the Board a priority and think that it will become an important element of decision-making when the Company comes to a critical juncture.

Since Seikagaku is a pharmaceutical company, its very existence depends on rapidly and outside directors to be performance of management oversight mainly from two perspectives. The first is to confirm that a structure has been set up to ensure that new drug development is not delayed due to misconduct or error. The second is to confirm that an environment and structure have been improved to enable motivated employees to actively play a part in creating new drugs. I want to make possible sustained growth and contribute to making Seikagaku a better company through these activities.

Mie Fujimoto
Outside Audit & Supervisory Board Member

Further fostering a corporate culture of honesty and integrity

Outside Audit & Supervisory Board members are expected to have a high degree of independence and apply perspectives and experience unavailable within the company in the conduct of audits. Seikagaku's outside Audit & Supervisory Board members attend the Board and inquire about accounting audit plans and results. Our activities include deepening our understanding of management policies and issues through conversations with the president & CEO, conducting interviews about business execution with division and department managers, receiving reports on internal audits from the Audit Department, and ascertaining manufacturing plant issues by attending management reviews. I myself point out risks and matters for concern in business execution based on my experience as an attorney specialized in labor and business law and as an outside officer of other companies.

Although compliance is important for a company in any business field, for Seikagaku in particular, as a pharmaceutical company, the occurrence of a regulatory compliance violation could turn into a problem that rocks the foundation of the business. I believe that the most important thing for ensuring compliance is a corporate culture of honesty and integrity. I feel that Seikagaku has such a corporate culture, starting from the attitude of top management. However, this culture must be fostered through daily effort. In my role as an outside Audit & Supervisory Board member, I will strive to further promote compliance at Seikagaku and, by extension, contribute to enhancement of corporate value, in close cooperation with the full-time Audit & Supervisory Board members.

BUSINESS RISKS

Risk Management System

Seikagaku has established business risk management regulations and developed a system to ascertain and manage risks pertaining to business execution.

We have established the Risk Management Committee, chaired by the chief risk management officer (the member of the Board in charge of Corporate Strategy, Human Resources, Finance and Accounting, and Corporate Staff) and comprising the executive vice presidents in charge of various departments. The Committee deliberates risk prevention measures and, when a material business risk event occurs, establishes a response headquarters and takes measures to minimize damage.

Business Risks

The following are the principle risks we recognize that could have a material effect on the operating results and the financial situation of the Seikagaku Group.

Legal restrictions, healthcare system, and administrative trends

Many Seikagaku Group products affect lives and health and, consequently, are subject to legal restrictions for ensuring the quality, efficacy, and safety of pharmaceuticals and other products imposed by regulatory authorities in Japan and other countries. Amendments to these related laws and regulations or healthcare system and administrative policies, including revisions to the National Health Insurance Drug Price Standard, could affect our business results.

The Company's policy is to promptly ascertain the details of revisions and appropriately respond to risks arising from revisions to statutory regulations, etc. by constantly monitoring regulatory trends. Nevertheless, the Seikagaku Group cannot determine the details or timing of those revisions or of drug prices or prescription changes, and we recognize that it is difficult to assess their impact in advance.

New product development

In pharmaceutical product development, the core of Seikagaku's business, various clinical studies to confirm efficacy and safety are required from the time of basic research to new drug approval. Even if the Company bears enormous R&D expenses over long periods of time, there is risk that products under development will not progress to launch. R&D expenses vary according to R&D progress, and this could affect our business results. In such an event, it may not be possible to earn profits commensurate with R&D expenses recorded in prior periods. The Company is striving to diversify risk by strengthening the research and development system and maintaining multiple development pipelines in order to satisfy unmet medical needs. Nevertheless, this does not enable us to avoid all risks, and any such uncertainty in new product development could affect our business results.

Reliance on specific distributors

We have entered into exclusive distributorship agreements with sales partners for the pharmaceuticals and medical devices that are our mainstay products, which limits the number of distributors. Changes to the business relationships with these companies due to changes in circumstances, depending on the nature of the changes, could affect our business results. Also, we recognize that it is difficult to assess the impact of materialization of this risk.

Risks related to side effects

Prescription drugs and medical devices entail the risk of emergence of unanticipated side effects from the clinical trial stage to the post-marketing stage. Materialization of this risk could lead to delays in clinical trials or discontinuation of development of a product in development. Also, an unanticipated side effect in an approved product could develop into a situation such as suspension of sale or a product recall, which could affect our business results.

Reliance on specific suppliers

Various restrictions apply to the manufacture of pharmaceuticals and medical devices, and some raw materials require the approval of regulatory authorities. Therefore, the number of raw materials suppliers is limited, and we perform on-site audits and strive to maintain quality and establish a stable supply system. We rely on a single supply sources for some raw materials. Consequently, any change in circumstances that makes it difficult to procure raw materials would pose the risk of disruption to the manufacture of products. Although we have taken measures to minimize any impact on business results by appropriately holding raw materials and product inventory, materialization of such a risk could affect our business results. The impact of materialization of such a risk will vary substantially depending on the product in question, the availability of replacement materials, the time required for procurement, and other factors, and we recognize that it is difficult to assess the impact in advance.

Use of animal-derived ingredients as raw materials

Many of the Seikagaku's products are made using ingredients derived from animals, namely chickens, sharks, and horseshoe crabs, as raw materials. Consequently, any restrictions on the use of animal-derived ingredients as raw materials or difficulty in procuring these ingredients could affect our business results.

The Seikagaku Group diversifies suppliers to the extent possible and takes measures to minimize any impact on business results by appropriately holding raw materials and product inventory. We are also developing products that use fermented raw materials and developing clinical trial methods that use genetically modified organisms and are striving to minimize risk. Nevertheless, these measures do not enable us to avoid all risks, and we recognize that materialization of a risk would unavoidably affect our business results to a certain degree.

Exchange rate fluctuations

The overseas sales ratio in fiscal 2019 was 45.1%, and many overseas sales transactions are denominated in U.S. dollars and other foreign currencies. Consequently, any sudden exchange rate fluctuations could affect our business results. For this reason, the Company strives to mitigate the risk of exchange rate fluctuations by allocating foreign currency sales proceeds to payment of R&D expenses, such as expenses for clinical trials conducted overseas, and entering into foreign exchange contracts. Nevertheless, we recognize that it is difficult to completely avoid risk in this way. Also, when preparing the consolidated financial statements, we convert financial statements of overseas consolidated subsidiaries denominated in local currencies to yen. Consequently, exchange rate trends could affect our business results.

Price fluctuations of holdings of marketable securities

We invest cash reserves in marketable securities for the purpose of applying them to future R&D and capital expenditures. Although we endeavor to reduce risks through diversification of investments and other means, price fluctuations of marketable securities and other investments could affect our business results. It is difficult to mitigate or eliminate external risks arising from trends in financial markets and monetary policy using risk mitigation measures specific to Seikagaku. For this reason, we believe that the Group would be affected if such risks materialize, depending on the timeframe and scale, and recognize that it is difficult to quantitatively assess the impact of materialization.

Intellectual property rights

Although we have filed various applications to secure patent rights and other intellectual property rights in order to secure competitive advantage for products and businesses, any inability to obtain patent or other rights, denial of the validity or exclusivity of patent or other rights that have been obtained, or expiration of the term of patent or other rights could affect our business results. Also, although we conduct research to avoid infringement of third-party intellectual property rights and minimize the possibility of infringement, it is difficult to completely avoid intellectual property right infringement problems, and the occurrence of a dispute with a third party concerning intellectual property rights could affect our business results. Also, we recognize that it is difficult to quantitatively assess the impact of future materialization at this time.

Occurrence of large-scale disasters

Any stagnation of business activities or disruption of product supply as a result of extensive damage to the Seikagaku Group's business sites due to an earthquake, a typhoon or other natural disaster, fire or other accident, or an epidemic of a new influenza virus or other infectious disease could affect our business results. Also, any major expenses for the repair of facilities damaged in a disaster could affect our business results. Although the Seikagaku Group has taken advance measures, including preparation of manuals for responding to various natural disaster risks, these risks cannot be avoided solely by the Group's risk management measures, the Group could be affected if risks materialize, according to the scale, timeframe, or other factors, and we recognize that it is difficult to quantitatively assess the impact of materialization.

Novel coronavirus (COVID-19) pandemic

Many Seikagaku Group's products affect people's health, and for this reason, we ordinarily secure appropriate inventory quantities, so even if manufacturing or distribution is temporarily disrupted, there is no problem with product supply. On the other hand, any prolongation of the decline in prescription demand for joint function improving agents in Japan and the U.S., our main markets, due to people staying at home or other factors could affect our business results. Also, our clinical trials are being affected by factors such as subject enrollment delays and suspension of acceptance of patients at some clinical trial sites as part as the response to COVID-19 at medical institutions in Japan and abroad, and any prolongation of these factors could also affect the launch timing of new drugs in development and affect our business results. This risk cannot be eliminated solely by the Group's risk management measures, and we believe that our clinical trials will be substantially affected by the further spread of COVID-19 and the time required until it subsides, the countermeasure policies of national governments, and other factors. For this reason, we recognize that it is difficult to quantitatively assess the impact of materialization.

SOCIAL CONTRIBUTION ACTIVITIES

Seikagaku engages in initiatives to address social and environmental problems in pursuit of harmony and continuous growth together with local communities.

Ibaraki-no-Kusuriten (Ibaraki Medicine Exhibition) disseminates correct knowledge of medicine

Seikagaku exhibited at Ibaraki-no-Kusuriten in October 2019, a medicine exhibition hosted by Ibaraki Prefecture each year to coincide with Medicine and Health Week. The purpose of Ibaraki-no-Kusuriten (Ibaraki Medicine Exhibition) is to inform the general public of the importance of correctly using medicines through an exhibition that introduces pharmaceuticals, medical devices, quasi-drugs, and other products produced at plants in Ibaraki Prefecture and events, such as a quiz rally to deepen understanding of medicine and a participatory simulation of prescription filling.

Since Seikagaku has a pharmaceutical manufacturing plant in Takahagi City, Ibaraki Prefecture, we have a display area at the exhibition each year where Takahagi Plant and Business Development & Marketing Division employees introduce visitors to Seikagaku's business activities and the characteristics of hyaluronic acid and promote awareness of diseases addressed by Seikagaku products with the aim of promoting understanding of the role Seikagaku products play in everyday life. The exhibition serves as an opportunity for employees to experience a sense of responsibility for our products while at the same time spreading proper understanding of pharmaceuticals.

Explaining the characteristics of hyaluronic acid and Seikagaku products

The Seikagaku display area

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, and already had started with organizations in China and Malaysia. Organizations receiving assistance will be granted a license to use ACC proprietary technology and expertise free of charge, and they are provided customized tools, instruction in 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 exceeded 800,000 in 2020. The Seikagaku Group will continue to promote activities to conserve and sustain horseshoe crab populations worldwide, and strive to use this precious resource in a sustainable, responsible manner.

* Endotoxin-detecting reagents used in quality control for manufacturing processes of pharmaceuticals and medical devices

Released American horseshoe crabs

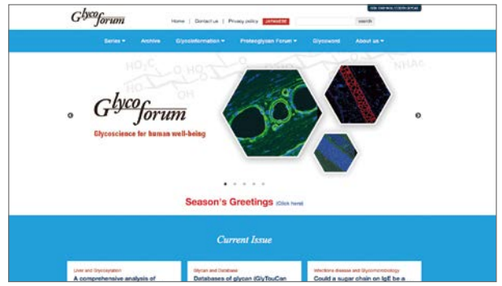
Seikagaku pursues respect for learning by engaging in global research assistance and sponsoring activities that support the development of glycoscience.

Glycoforum, a website for comprehensive information on glycoscience research

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

Since 1997, Seikagaku has operated "Glycoforum," an academic website 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 promptly disseminates science paper information, including commentary from global leading researchers and academic conference information. The site enjoys strong support from researchers in Japan and overseas.



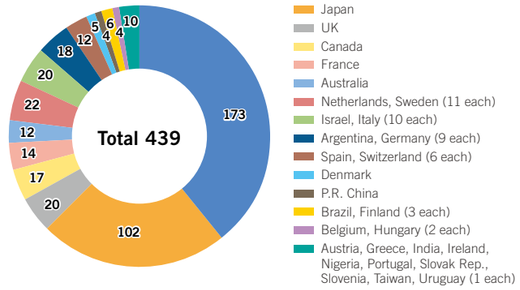
Support for the Mizutani Foundation for Glycoscience

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

The Mizutani Foundation for Glycoscience 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 2019, the Foundation provided research grants totaling approximately ¥66.8 million to 16 grant recipients.

Seikagaku endorses the purpose of the Foundation and has continuously supported its activities since its founding.

Number of Grant Recipients by the Mizutani Foundation for Glycoscience (By country and area: 1993–2020)



Promoting early treatment of knee osteoarthritis *Hiza Ikiiki* (Sprightly Knees), a website for provision of information concerning knee osteoarthritis to the general public

Hiarun-Kun

https://www.ehiza.jp

Some 30 million patients* in Japan are said to suffer from knee osteoarthritis, a disorder marked by knee joint strain due to aging, excessive exercise, or weight increase causing the cartilage to gradually wear away. The *Hiza Ikiiki* website explains basic knowledge concerning knee osteoarthritis, diagnosis, and treatment methods in an easy to understand way and gives information on nearby medical institutions that operate outpatient clinics and provide treatment for knee pain. Visitors can also download a pamphlet "Exercise therapy of knee osteoarthritis."

We will provide correct knowledge to people with knee pain and further enhance website content to enable greater numbers to promptly obtain appropriate treatment.

* "Locomotive Disorder Countermeasures to Promote Preventive Care," a report from the Ministry of Health, Labour and Welfare issued in 2008

CONSOLIDATED 10-YEAR SUMMARY

(Millions of yen / %)

	2011/3	2012/3	2013/3	2014/3	2015/3	2016/3	2017/3	2018/3	2019/3	2020/3
Net Sales*1	27,117	27,082	26,639	29,614	29,522	30,962	29,589	30,175	28,384	28,642
Overseas Sales	5,710	6,035	6,311	8,802	9,997	11,581	11,029	12,051	11,966	12,913
Cost of Sales	10,480	9,748	9,867	11,223	12,130	12,871	13,247	13,008	13,114	12,513
Selling, General and Administrative Expenses	13,103	12,716	13,645	13,452	15,008	15,946	15,059	15,745	14,292	14,169
R&D Expenses	6,723	5,970	6,838	6,588	8,146	8,649	7,834	8,408	7,148	6,877
Operating Income	3,533	4,617	3,126	4,937	2,383	2,144	1,282	1,421	977	1,960
Ordinary Income	4,159	4,770	4,302	5,878	4,008	3,500	2,477	5,327	2,859	3,981
Net Income	2,451	3,270	3,256	4,745	3,650	2,578	1,787	3,922	2,244	(10,839)
Total Equity	56,106	58,013	61,316	64,785	70,410	69,815	70,646	73,945	73,036	59,767
Total Assets	62,684	68,730	70,471	73,826	80,889	80,218	80,048	84,098	80,238	68,501
Overseas Sales Ratio	21.1	22.3	23.7	29.7	33.9	37.4	37.3	39.9	42.2	45.1
Cost of Sales Ratio	38.6	36.0	37.0	37.9	41.1	41.6	44.8	43.1	46.2	43.7
Selling, General and Administrative Expenses Ratio	48.3	47.0	51.2	45.4	50.8	51.5	50.9	52.2	50.4	49.5
R&D Expenses Ratio	24.8	22.0	25.7	22.2	27.6	27.9	26.5	27.9	25.2	24.0
Operating Income Ratio	13.0	17.0	11.7	16.7	8.1	6.9	4.3	4.7	3.4	6.8
Ordinary Income Ratio	15.3	17.6	16.1	19.8	13.6	11.3	8.4	17.7	10.1	13.9
Net Income Ratio	9.0	12.1	12.2	16.0	12.4	8.3	6.0	13.0	7.9	—
Return on Equity (ROE)*2	4.4	5.7	5.5	7.5	5.4	3.7	2.5	5.4	3.1	(16.3)
Return on Assets (ROA)*2	6.6	7.3	6.2	8.1	5.2	4.3	3.1	6.5	3.5	5.4
Turnover of Total Assets*2	0.43	0.41	0.38	0.41	0.38	0.38	0.37	0.37	0.35	0.39
Shareholders' Equity Ratio	89.5	84.4	87.0	87.8	87.0	87.0	88.3	87.3	91.0	87.2
Number of R&D Personnel	224	221	224	215	216	221	222	233	233	242
R&D Personnel Ratio	34.5	34.3	34.9	33.6	33.3	33.3	32.3	32.5	31.3	27.9
Number of Employees	649	644	641	639	649	663	687	718	744	868
Amount of Capital Expenditure	1,306	5,718	9,164	7,222	2,095	1,975	1,173	1,591	1,310	2,109
Depreciation and Amortization	2,336	2,008	2,175	1,767	2,610	3,191	2,920	2,925	2,902	1,778
Net Income per Share	43.16	57.58	57.33	83.55	64.27	45.39	31.55	69.30	39.76	(192.15)
Total Equity per Share	987.67	1,021.24	1,079.38	1,140.48	1,239.51	1,229.05	1,248.07	1,306.37	1,294.88	1,059.40
Dividends per Share	25.00	25.00	25.00	26.00	26.00	26.00	31.00*3	26.00	26.00	26.00
Dividend Payout Ratio	57.9	43.4	43.6	31.1	40.5	57.3	98.3	37.5	65.4	—
Dividends as a Percentage of Total Equity (DOE)	2.5	2.5	2.4	2.3	2.2	2.1	2.5	2.0	2.0	2.2

*1 Until the prior fiscal year, ended March 31, 2011, the Company recorded milestone-type royalty income as sales. Effective April 1, 2010, the company has changed it to other income.
*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 Including a 70th anniversary commemorative dividend of ¥5 per share.

REVIEW OF OPERATIONS (April 1, 2019–March 31, 2020)

Overall net sales and income

In the fiscal year ended March 31, 2020 (fiscal 2019), net sales were ¥28,642 million, up 0.9% year on year. The result is attributable to growth in sales in the overseas pharmaceuticals segment, which compensated for a decline in sales in the domestic pharmaceuticals segment due to the impact of National Health Insurance (NHI) drug price reductions. The overseas sales ratio was 45.1%, an increase of 2.9 points from the previous fiscal year.

Operating income rose 100.6% year on year to ¥1,960 million as a result of the sales increase coupled with a decrease in depreciation in connection with an impairment loss* and a year-on-year decrease in R&D expenses due to completion of clinical studies in Japan for SI-613, a treatment for osteoarthritis. Ordinary income rose 39.2% year on year to ¥3,981 million, reflecting a substantial increase in royalty income, while recorded loss on sale of investment securities. The Company recorded a net loss attributable to owners of parent of ¥10,839 million (compared to a net profit of ¥2,244 million during the same period in the previous fiscal year) due to the recording of an extraordinary loss (impairment loss)*.

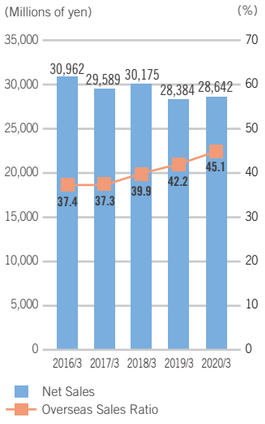
Total R&D expenses in fiscal 2019 decreased 3.8% year on year to ¥6,877 million, or 24.0% of net sales. R&D Expenses Ratio was 24.0%, a decrease of 1.2 points from the previous fiscal year.

* The Company recognized an impairment loss on property, plant and equipment related to the Pharmaceuticals business, and recorded extraordinary losses of ¥13,524 million in the fiscal year.

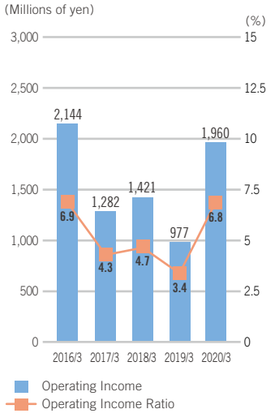
(Millions of yen)

	2019/3	2020/3	Year on Year
Net Sales	28,384	28,642	+0.9%
Operating Income	977	1,960	+100.6%
Ordinary Income	2,859	3,981	+39.2%
Net Income	2,244	(10,839)	—
R&D Expenses	7,148	6,877	–3.8%

Net Sales and Overseas Sales Ratio



Operating Income and Operating Income Ratio

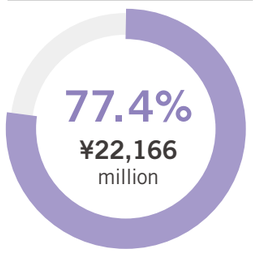


Net sales by segment

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 increased 1.2% year on year to ¥22,166 million, accounting for 77.4% of total sales.

Pharmaceuticals Business Sales Composition

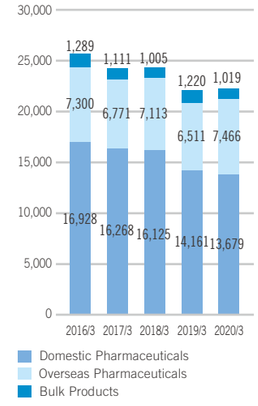


● Domestic Pharmaceuticals (¥13,679 million, down 3.4% year on year)

Deliveries to medical institutions of ARTZ, a joint function improving agent for knee osteoarthritis, decreased slightly due to contraction in the market overall, despite an increase in market share resulting from successful measures to acquire new user facilities. The Company's sales fell year on year, reflecting in part the impact of NHI drug price reductions. For the OPEGAN series of ophthalmic viscoelastic devices, deliveries to medical institutions and the Company's sales increased due to overall market expansion, progress in acquiring share from competing products, and a temporary increase in shipments attributable to suspension of shipments of a competing product. For MucoUp, a submucosal injection agent for endoscopic surgery, decreased in the Company's sales due to the impact of the introduction of competing products on the market.

For HERNICORE, a treatment for lumbar disc herniation, the Company's sales decreased as shipments declined from a high level the previous fiscal year due to secure distribution inventory, although deliveries to medical institutions were strong. To provide the opportunity for treatment to greater numbers of patients, the Company will continue to strive for steady market penetration while proceeding together with the sales partner with information provision activities directed at medical institutions to ensure appropriate use and safety and the collection of post-marketing safety information as the highest priority.

Sales of Pharmaceuticals Business



● Overseas Pharmaceuticals (¥7,466 million, up 14.7% year on year)

In the U.S. Gel-One, an intra-articular single-injection viscosupplement for the treatment of knee osteoarthritis, increased substantially both local sales volume and the Company's sales, as a result of qualification for preferential reimbursement status with multiple insurance companies beginning in 2019 and the impact of measures by the sales partner to promote switching from competing products. For SUPARTZ FX, an intra-articular 5-injection viscosupplement for the treatment of knee osteoarthritis, local sales volume and the Company's sales declined due to the impact of a continuing trend in the U.S. market toward preference for products that require a low number of injections. Regarding ARTZ in China (P.R.C.) local sales volume and the Company's sales decreased, reflecting factors including curtailment of outpatient services at medical institutions in response to the spread of the COVID-19 outbreak.

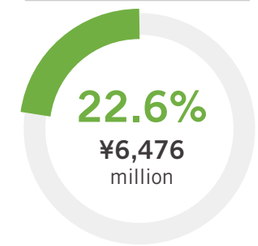
● Bulk Products (¥1,019 million, down 16.4% year on year)

The Company's sales decreased due to factors including intensification of competition for hyaluronic acid.

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 ¥6,476 million, down 0.2% from the previous fiscal year.

LAL Business Sales Composition



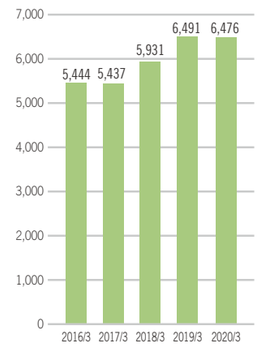
● LAL Business

Whereas sales of Bacterial Endotoxin Testing (BET) and Clinical Diagnostic (Fungitell) reagents increased thanks to reinforcement of sales activities at overseas subsidiary Associates of Cape Cod, Inc., sales in Japan declined. Consequently, sales of the LAL business were nearly unchanged from the previous fiscal year.

(Millions of yen)

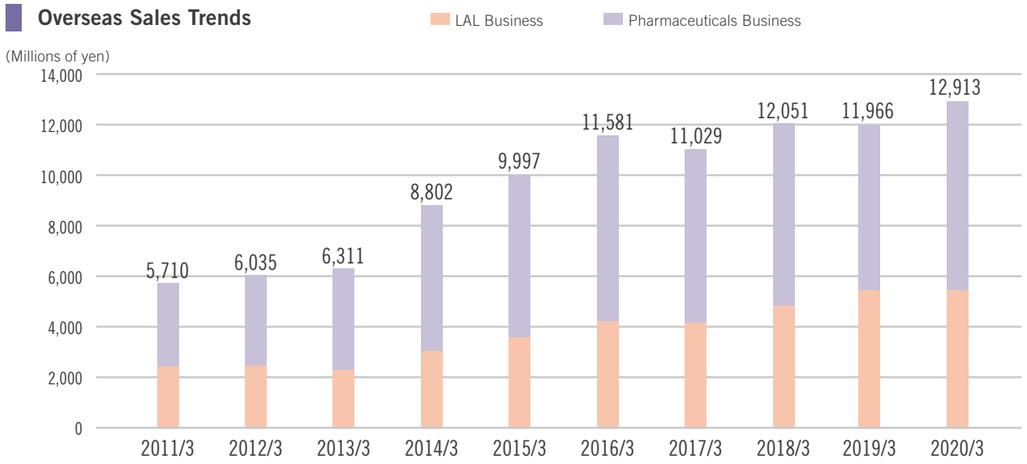
Sales by Segment	2019/3	2020/3	Year on Year
Pharmaceuticals Business	21,893	22,166	+1.2%
Domestic Pharmaceuticals	14,161	13,679	–3.4%
Overseas Pharmaceuticals	6,511	7,466	+14.7%
Bulk Products	1,220	1,019	–16.4%
LAL Business	6,491	6,476	–0.2%
Total	28,384	28,642	+0.9%
(Overseas Sales)	11,966	12,913	+7.9%

Sales of LAL Business

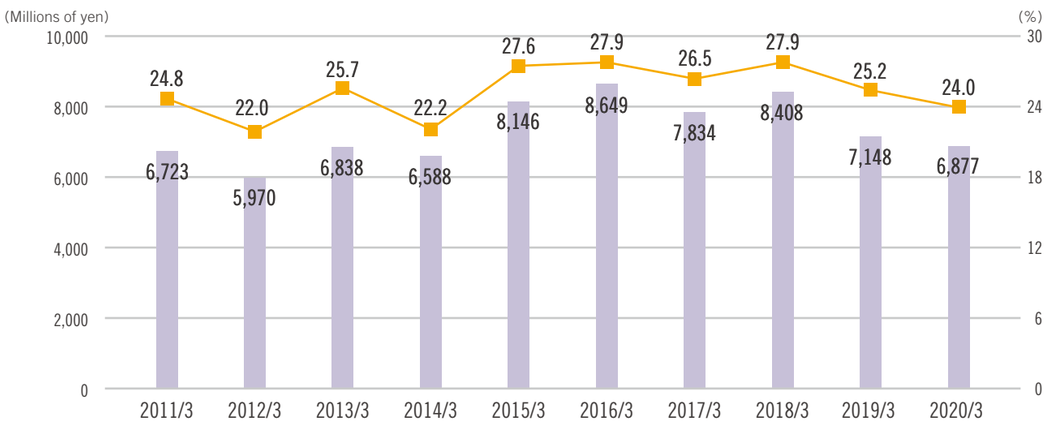


FINANCIAL / NON-FINANCIAL HIGHLIGHTS

Overseas Sales Trends

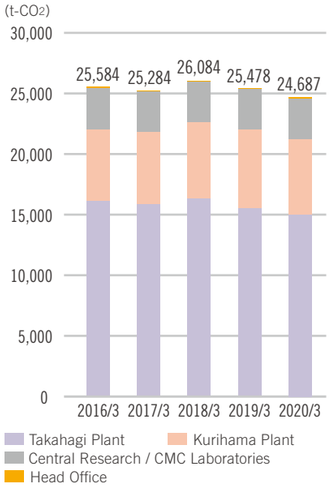


R&D Expense Trends

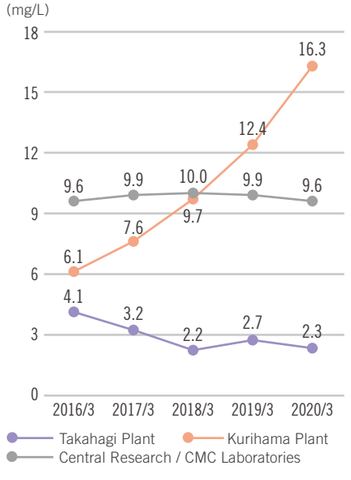


Non-financial Highlights (Non-consolidated Basis)

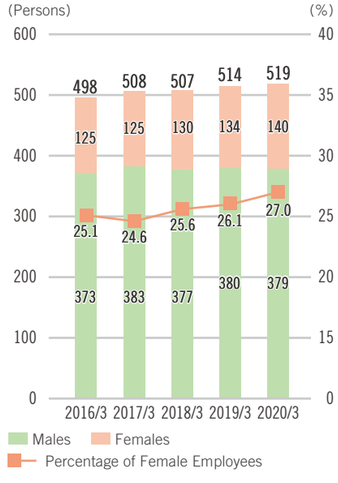
CO_2 Emissions



Water Pollution Load (COD)



Composition of Work Force



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. 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 230 employees and has operations in the U.K. and Germany.

ACC's reagent 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 that location, ACC also offers customers in-house contract testing services for BET and clinical glucan product testing.

Corporate Outline (As of March 31, 2020)

Paid-in Capital	$2,080
Ownership Ratio	100%
Business	Manufacturing and sales of endotoxin-detecting reagents
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*1) 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*2–compliant manufacturing site for pharmaceuticals and other products in Ontario, Canada. Dalton currently has approximately 120 employees.

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

*1 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.

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

Corporate Outline (As of March 31, 2020)

Paid-in Capital	CAD 49,800 thousand
Ownership Ratio	100%*3
Business	CDMO
URL	https://www.dalton.com/

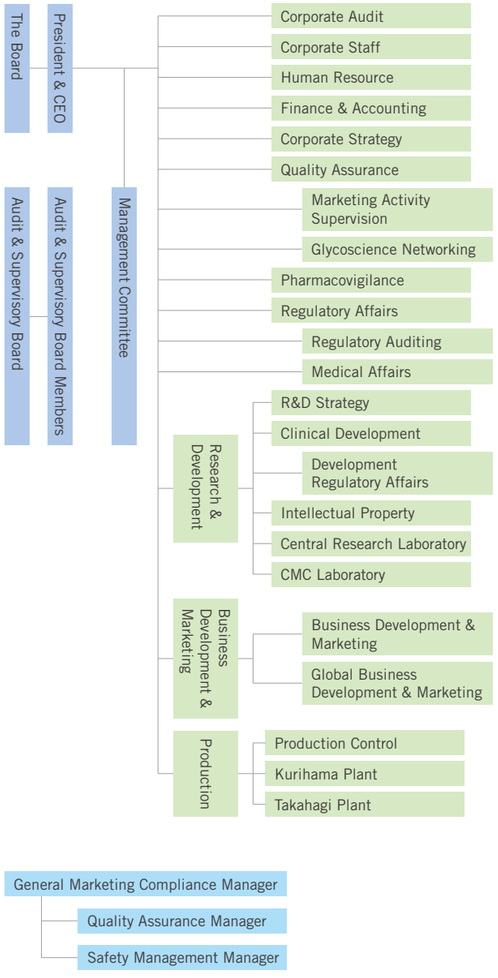
*3 Dalton is a wholly owned subsidiary of SKK CANADA ENTERPRISES CORPORATION, an intermediate holding company established in Canada by Seikagaku.

CORPORATE DATA

Overview (As of March 31, 2020)

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, First Section (Stock code: 4548)
URL	https://www.seikagaku.co.jp/en/
Number of Employees	868 (Consolidated)
Paid-in Capital	¥3,840 million
Net Sales	¥28,642 million (As of March 31, 2020)

Organization Chart (As of October 1, 2020)



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 Subsidiary

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, 2020)

Shares per Unit	100
Authorized Shares	234,000,000
Authorized Outstanding Shares	56,814,093
Number of Shareholders	9,939
General Shareholders' Meeting	June
Date of Record for Shareholders Eligible to Receive Dividends	March 31

Shareholder Registry Administrator

Mitsubishi UFJ Trust and Banking Corporation

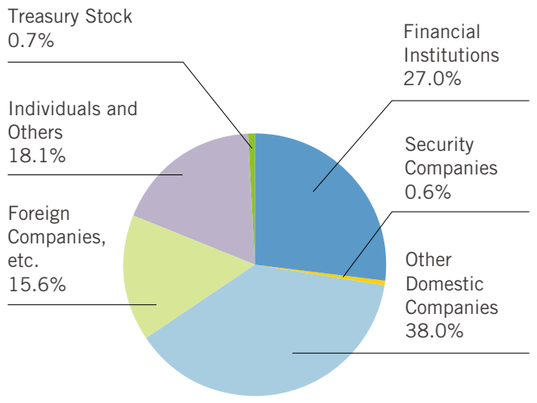
<Contact>
Mitsubishi UFJ Trust and Banking Corporation
Securities Agency Division
PO Box 29, New Tokyo Post Office, Tokyo 137-8081
Tel: 0120-232-711 (Domestic toll-free)

Major Shareholders (As of March 31, 2020)

	Name of Shareholders	Number of Shares Held (Thousands of Shares)	Percentage of Outstanding Shares (%)
1	Shingyo KK	7,843	13.9
2	KK Kaiseisha	7,293	12.9
3	The Master Trust Bank of Japan, Ltd. (Trust account)	3,679	6.5
4	Trust & Custody Services Bank, Ltd. as Trustee for Mizuho Bank, Ltd. Retirement Benefit Trust Account re-entrusted by Mizuho Trust and Banking Co, Ltd.	1,973	3.5
5	Japan Trustee Services Bank, Ltd. (Trust account 9)	1,843	3.3
6	MUFG Bank, Ltd.	1,536	2.7
7	The Bank of New York Mellon (International) Limited 131800	1,491	2.6
8	Japan Trustee Services Bank, Ltd. (Trust account)	1,310	2.3
9	Kaken Pharmaceutical Co., Ltd.	1,207	2.1
10	Mizutani Foundation for Glycoscience	828	1.5

Note: Treasury stock (397 thousand shares) is excluded from the calculations of the percentages above.

Breakdown of Shareholders by Type (As of March 31, 2020)



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 represents 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/

2021.2 (100)
Printed in Japan