May 13, 2025

SEIKAGAKU CORPORATION

Consolidated Financial Results (Japan GAAP) (Summary) for the Fiscal 2024 (Year Ended March 31, 2025)

Listed exchanges: Tokyo Stock Exchange (Prime Market)
Stock code number: 4548
URL: https://www.seikagaku.co.jp/en/
Date of ordinary general meeting of shareholders (Planned): June 20, 2025
Date of dividend payment (Planned): June 23, 2025

(All amounts have been rounded down to the nearest million yen)

1. Consolidated Financial Results for the Fiscal 2024(from April 1, 2024 to March 31, 2025)

(1) Consolidated Financial Results

(Percentages indicate changes from the prior fiscal year)

	Net sales		Operating income		Ordinary income		Net income attributable to owners of parent	
	Millions of Yen	%	Millions of Yen	%	Millions of Yen	%	Millions of Yen	%
Fiscal 2024	39,374	8.7	1,333	207.8	1,933	14.3	1,214	(44.5)
Fiscal 2023	36,213	8.2	433	(79.5)	1,691	(44.9)	2,186	(2.2)

(Note) Comprehensive income:
Fiscal 2024: 2,417 million yen [(62.6)%]
Fiscal 2023: 6,469 million yen [65.0 %]

	Net income per share	Diluted net income per share	Return on equity	Ordinary income as a percentage of total assets	Operating income as a percentage of net sales
	Yen	Yen	%	%	%
Fiscal 2024	22.25	-	1.7	2.3	3.4
Fiscal 2023	40.08	-	3.1	2.1	1.2

(2) Consolidated Financial Position

	Total assets	Total equity	Equity ratio	Total equity per share
	Millions of Yen	Millions of Yen	%	Yen
Fiscal 2024	83,872	73,187	87.3	1,340.98
Fiscal 2023	81,795	72,282	88.4	1,324.82

(Reference) Shareholders' Equity:
Fiscal 2024: 73,187 million yen
Fiscal 2023: 72,282 million yen

(3) Consolidated Cash Flows

	Net cash flows from operating activities	Net cash flows from investing activities	Net cash flows from financing activities	Cash and cash equivalents at the end of fiscal year
	Millions of Yen	Millions of Yen	Millions of Yen	Millions of Yen
Fiscal 2024	4,429	(3,540)	(1,571)	18,322
Fiscal 2023	513	(7,209)	(1,461)	18,701

2. Dividends

	Dividends per share				
	1st Quarter	2nd Quarter	3rd Quarter	Fiscal Year-end	Annual
	Yen	Yen	Yen	Yen	Yen
Fiscal 2023	-	13.00	-	13.00	26.00
Fiscal 2024	-	15.00	-	15.00	30.00
Fiscal 2025 (Forecast)	-	15.00	-	15.00	30.00

	Total dividend payments (Annual)	Dividend payout ratio (Consolidated)	Dividends as a percentage of total equity (Consolidated)
	Millions of Yen	%	%
Fiscal 2023	1,418	64.9	2.0
Fiscal 2024	1,637	134.8	2.3
Fiscal 2025 (Forecast)		121.3	

3. Forecast of Consolidated Financial Results for Fiscal 2025 (from April 1, 2025 to March 31, 2026)

(Percentages indicate changes from the prior fiscal year)

	Net sales		Operating income		Ordinary income		Net income attributable to owners of parent		Net income per share
	Millions of Yen	%	Millions of Yen	%	Millions of Yen	%	Millions of Yen	%	Yen
Fiscal 2025	35,600	(9.6)	(300)	-	1,350	(30.2)	1,350	11.2	24.74

* Notes

(1) Changes in the status of material subsidiaries during the period: No

(2) Changes in accounting principles, changes in accounting estimates, and retrospective restatements

(a) Changes in accounting principles accompanying revisions in accounting standards: Yes
(b) Changes other than those in (a) above: No
(c) Changes in accounting estimates: No
(d) Retrospective restatements: No

(3) Number of shares issued (common stock):

(a) Number of shares at the end of the period (including treasury stock)
(b) Number of treasury stock at the end of the period
(c) Average number of shares issued during the period

As of March 31, 2025	56,814,093 shares	As of March 31, 2024	56,814,093 shares
As of March 31, 2025	2,236,456 shares	As of March 31, 2024	2,253,745 shares
Fiscal 2024	54,572,641 shares	Fiscal 2023	54,554,782 shares

(Reference) Non-Consolidated Financial Results

Non-Consolidated Financial Results for Fiscal 2024 (from April 1, 2024 to March 31, 2025)

(1) Non-Consolidated Financial Results

(Percentages indicate changes from the prior fiscal year)

	Net sales		Operating income		Ordinary income		Net income	
	Millions of Yen	%	Millions of Yen	%	Millions of Yen	%	Millions of Yen	%
Fiscal 2024	26,620	5.9	440	-	1,302	(27.8)	922	(63.6)
Fiscal 2023	25,141	13.8	(332)	-	1,804	(2.2)	2,537	41.1

	Net income per share	Diluted net income per share
	Yen	Yen
Fiscal 2024	16.90	-
Fiscal 2023	46.50	-

(2) Non-Consolidated Financial Position

	Total assets	Total Equity	Equity ratio	Total Equity per share
	Millions of Yen	Millions of Yen	%	Yen
Fiscal 2024	66,509	59,269	89.1	1,085.96
Fiscal 2023	66,686	60,314	90.4	1,105.46

(Reference) Shareholders' Equity:

Fiscal 2024: 59,269 million yen

Fiscal 2023: 60,314 million yen

***This financial reports are not subject to audit of the certified public accountant and audit firm.**

***The above forecast has been prepared on the basis of economic circumstances, market trends, and other assumptions made at the time of release of this document. Actual results may differ from the forecast due to a variety of factors.**

1. Analysis of Results of Operations

Results of operations for the current fiscal year

In the fiscal year ended March 31, 2025 (fiscal 2024), net sales were ¥39,374 million, up 8.7% year on year. The increase is attributable to higher royalty income and higher sales in the LAL business, despite lower sales of domestic and overseas pharmaceuticals. Operating income rose 207.8% year on year to ¥1,333 million because of the revenue increase. Ordinary income rose 14.3% year on year to ¥1,933 million, which lagged behind operating income growth because of the recognition of foreign exchange loss, and net income attributable to owners of parent fell 44.5% to ¥1,214 million due to higher tax expenses.

1) Net sales by segment

Pharmaceutical Business

Seikagaku has adopted a business model of focusing management resources on R&D and manufacturing by forming alliances with domestic and overseas companies that have expertise in each product field and entrusting sales to these business partners rather than having an in-house pharmaceuticals sales division.

In view of this business structure, in addition to reporting product sales from Seikagaku to business partners, the Company also reports on the status of sales from business partners to medical institutions using "deliveries to medical institutions" or "local sales volume" as performance indicators.

- Domestic Pharmaceuticals (¥11,919 million, down 1.5% year on year)

Revenue from domestic pharmaceuticals fell 1.5% year on year, mainly because of lower sales of ARTZ, a joint function improvement agent for knee osteoarthritis, and the OPEGAN series of ophthalmic viscoelastic devices.

Deliveries to medical institutions of ARTZ rose sharply year on year thanks to continued switching from competing products. Also, facilities maintenance for the purpose of production system expansion at the Company's plant was completed, and shipment volume increased year on year. However, the Company's sales declined year on year due to a decrease in unit prices reductions.

Deliveries to medical institutions of the OPEGAN series increased year on year, reflecting factors including a continued gradual market growth trend accompanying population aging. Nevertheless, the Company's sales fell year on year, due to a decline in unit prices.

The Company's sales of HERNICORE, a treatment for lumbar disc herniation, declined year on year due to shipment timing, while sales of MucoUp, a submucosal injection agent for endoscopic surgery, decreased due to the impact of an insurance reimbursement price decrease.

The Company's sales of the joint function improvement agent JOYCLU rose year on year due to shipment timing. The Company issued a Dear Healthcare Professionals Letter of Rapid Safety Communication (Blue Letter) concerning JOYCLU on June 1, 2021 and is continuing cooperative efforts with sales partner Ono Pharmaceutical Co., Ltd. to gather side effects reports and other information and provide safety-related information.

- Overseas Pharmaceuticals (¥9,804 million, down 2.5% year on year)

Revenue from overseas pharmaceuticals fell 2.5% year on year due to lower sales of Gel-One, an intra-articular single-injection viscosupplement for the treatment of knee osteoarthritis for the U.S. market and ARTZ for China, despite higher sales of SUPARTZ FX, an intra-articular 5-injection viscosupplement for the treatment of knee osteoarthritis for the U.S. market.

Local sales volume of Gel-One declined year on year. The Company's sales decreased due to postponement of the shipment timing of certain products to fiscal 2025.

Although local sales volume of SUPARTZ FX, a product for the U.S. market, was at the prior-year level, the Company's sales rose year on year, reflecting distributor inventory adjustments.

Local sales volume of ARTZ for China declined year on year. The Company's sales for China also declined year on year due to a decrease in shipment volume accompanying a change of materials in the fourth quarter.

- Bulk Products and Contract Development and Manufacturing Organization (¥3,192 million, up 3.5% year on year)

Net sales from these businesses increased 3.5% year on year. Although sales of bulk products declined, sales of contract development and manufacturing and other services of overseas subsidiary Dalton Chemical Laboratories, Inc. increased.

As a result of these developments, coupled with an increase in royalty income (¥2,598 million, up 271.6% year on year), sales from the Pharmaceutical business segment rose 6.1% year on year to ¥27,513 million.

LAL Business

Sales from the LAL business segment increased 15.5% year on year to ¥11,860 million. The beneficial impact of yen depreciation and higher sales of Fungitell (a beta-glucan-detecting in vitro diagnostic) and PyroSmart NextGen recombinant reagent for endotoxin detection at overseas subsidiary Associates of Cape Cod, Inc., as well as strong sales in Japan, contributed to the sales increase.

2) Research and Development Activities

To contribute to healthy and fulfilling lives for people around the world, the Seikagaku Group focuses its research and development on glycoscience as its area of specialization and aims to create original pharmaceuticals and medical devices.

The Group will aim to achieve early and continuous launching of new products, which hold the key to future business growth, by focusing on application of Seikagaku's original glycoscience-related basic technologies to create new development themes in existing fields as well as innovative research themes, including in new disease areas, and by pursuing various alliances.

Total R&D expenses in fiscal 2024 were ¥7,643 million, or 20.8% of net sales (excluding royalties), and the number of R&D personnel was 201, or 18.7% of the total number of employees, at March 31, 2025.
The status of progress of principal R&D activities is described below.

SI-6603 (treatment for lumbar disc herniation: developed in the U.S.)

In March 2025, the Company received from the U.S. Food and Drug Administration (FDA) a complete response letter (CRL), and approval for SI-6603 was not obtained. The FDA expressed no concerns relating to the clinical study results, including the efficacy and safety of SI-6603, and no additional clinical studies are required. However, they did make additional observations, mainly concerning the manufacturing facility and control of the drug substance and drug product. The Company will now respond to the observations in preparation for obtaining approval at an early date and aim to resubmit an application within one year of receipt of the CRL.

SI-6603, which contains condoliase as its active pharmaceutical ingredient, is a therapeutic agent directly injected into the lumbar disc. It does not require general anesthesia and is less invasive to the patient than surgical treatment. Since a single-injection treatment is expected to improve the symptoms of lumbar disc herniation, the Company aims to provide SI-6603 as a new treatment option.

Gel-One (treatment for Osteoarthritis of the knee and hip: developed in Japan)

Gel-One is an intra-articular injection whose active ingredient is a cross-linked hyaluronate, utilizing Seikagaku's unique cross-linking technology. Since Gel-One remains in the joint for a long period of time, a single injection of Gel-One is expected to provide long-term pain relief. The product has been available in overseas markets since 2012 as Gel-One® (U.S.) and HyLink® (Taiwan and Italy) indicated for osteoarthritis of the knee.

Gel-One Initiated Phase III clinical studies of the knee joint and hip joint in February 2025.

SI-722 (treatment for interstitial cystitis: developed in the U.S.)

Seikagaku is considering the policy on future development based on data obtained in Phase I/II clinical studies.
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.

SI-449 (adhesion barrier: developed in Japan)

In a pivotal study in the field of gastroenterological surgery being conducted since May 2020, results showing statistically significant adhesion prevention performance in both the primary effectiveness endpoint of the presence or absence of post-operative adhesions and the secondary effectiveness endpoints of severity and extent of adhesions were obtained in July 2023. No safety issues were observed.

Also, no major problems were found with safety and operability of SI-449 in laparoscopic surgery in a pilot study in the field of gynecology conducted for the purpose of expanding the scope of indications for the product. The Company is currently proceeding with sales partner selection and construction of commercial production facilities and is making preparations with the aim of submitting an NDA during the third to fourth quarter of the fiscal year ending March 31, 2026.

SI-449 is a powdered medical device whose main ingredient is cross-linked chondroitin sulfate developed using Seikagaku's own proprietary glycosaminoglycan cross-linking technology. It has the property of absorbing moisture and swelling, and is expected to prevent post-operative adhesion formation in surgery by forming a barrier between the surgical wound site and surrounding tissues after application. The Company will proceed with development of SI-449 with a view to introducing it globally, not only in Japan.

SI-614 (treatment for dry eye: developed in the U.S.)

Statistically significant improvement in the primary endpoint of a Phase III clinical study being conducted since May 2022 was not observed. Accordingly, the Company decided to discontinue development of SI-614.

SI-613 (treatment for osteoarthritis: developed in the U.S., China, and South Korea)
SI-613-ETP (treatment for enthesopathy: developed in Japan)

SI-613

The Company decided to discontinue development of SI-613 in the U.S., China, and South Korea in light of progress with identification of the cause of shock or anaphylaxis associated with JOYCLU in Japan.

SI-613-ETP

The Company decided to discontinue development of SI-613-ETP in Japan in light of failure to meet the primary efficacy endpoint in a late-stage Phase II clinical trial in Japan of SI-613-ETP for the treatment enthesopathy and the state of progress with identification of the cause of shock or anaphylaxis associated with JOYCLU in Japan.

2. Forecasts for Fiscal 2025

For fiscal 2025 (April 1, 2025 to March 31, 2026), the Company forecasts consolidated net sales of ¥35,600 million, a decrease of 9.6% from the previous year. Although the main factor contributing to the projected revenue decrease is an expected decline in royalty income, lower sales of overseas pharmaceuticals and the LAL business attributable to yen appreciation are also projected.

As for the earnings outlook, the Company forecasts an operating loss of ¥300 million due to a decrease in revenue, ordinary income of ¥1,350 million because of the sale of investment securities, a decline of 30.2%, and net income attributable to owners of parent of ¥1,350 million, an increase of 11.2%.

The Company Forecasts R&D expenses of ¥7,000 million, a decrease of 8.4% year on year, and a ratio of R&D expenses to net sales (excluding royalty income) of 19.7%.

The exchange rate assumption used in the forecast of consolidated financial results for fiscal 2025 is ¥140 to the U.S. dollar.

Note: The above forecast has been prepared on the basis of economic circumstances, market trends, and other assumptions made at the time of release of this document. Actual results may differ from the forecast due to a variety of factors.

3. Issues Facing the Company

While the abrupt changes to the business environment surrounding the pharmaceuticals industry are continues to be extremely difficult, progress in measures to control medical expenses of starting with a drastic reform of the NHI drug pricing system in Japan, intensity of competition among firms the diversifying of treatment options, and degree of difficulty of new drug development increases in the inside cost of research and development which rises. A flexible response to these times of drastic change in the operating environment will be necessary for Seikagaku to maintain a constant growth trajectory. Also, fulfilment of social responsibilities, starting with sustainability promotion, is increasingly important for the sustainable development of society and enhancement of corporate value, and responding to this societal trend is a matter of urgent importance.

Overview of the mid-term management plan (fiscal 2022 to fiscal 2025)

1) Business Goal

Seikagaku has positioned the period of the current mid-term management plan, the four-year period beginning with the fiscal year ended March 31, 2023 (fiscal 2022), as a period for achieving growth. Building on a foundation solidified during the period of the previous management plan, Seikagaku aims to cultivate the ability to maintain a constant growth trajectory and achieve record-high business results in the final year of the plan by implementing key measures set out in the plan.

2) Key measures

Seikagaku will implement the following five key measures to nurture the capability to maintain a constant growth trajectory.

① **Maximize the product value of SI-6603 (treatment for lumbar disc herniation)**

Take maximum advantage of SEIKAGAKU NORTH AMERICA CORPORATION, established in Canada for the purpose of obtaining approval in the U.S. and launching SI-6603, a treatment for lumbar disc herniation, to ensure a prompt and accurate NDA and response to regulatory review. Also proceed with sales preparations and pursue maximization of product value through early penetration at medical institutions in close cooperation with the sales partner.

② **Accelerate R&D utilizing unique drug-discovery technologies**

Apply Seikagaku's own GAG*-related basic technologies to create new drugs that patients truly need, with an emphasis on unmet medical needs, by focusing on creation of new development themes in existing fields and creation of innovative research themes, including in new disease areas. Also, to increase the probability of success of these efforts, pursue various alliances aimed at making early progress. At the same time, advance existing pipelines with the aim of obtaining approval and introducing in the U.S. SI-6603 (a treatment for lumbar disc herniation), completing a Phase III clinical study in the U.S. of SI-614 (a treatment for dry eye), and obtaining approval in Japan and initiating a clinical study in the U.S. of SI-449 (an adhesion barrier).

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

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

Strive to maintain and enhance the business potential of the core products that support business management by increasing the presence of Seikagaku products in the mainstay domestic market for joint function improving agents. Since the domestic pharmaceuticals business is greatly affected by NHI drug price reductions, cost structure improvement is essential. Seikagaku will further proceed with product material specification changes, which help ensure continuity of product supply, manufacturing process efficiency improvement, and other measures. Seikagaku will also continue gathering and providing safety information on the joint function improving agent JOYCLU with the aim of contributing to appropriate prescription on the basis of clinical research findings.

④ **Construct a global production system**

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

⑤ **Expand the LAL business through recombinant technologies**

Aim to create new value in cooperation with overseas subsidiary Associates of Cape Cod, Inc. by accumulating reliable scientific data utilizing PyroSmart NextGen® recombinant LAL reagent and promoting development of new diagnostic reagents utilizing recombinant technologies and by developing and improving measurement equipment and software in collaboration with an affiliated company.

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

3) Sustainability

Seikagaku has identified six material issues as important issues that should be addressed on a priority basis in the interest of achieving sustainable development of society and enhancement of corporate value. Seikagaku will focus on these material issues, which are the foundation for the key measures in the mid-term management plan, strengthen development of medical-related businesses as well as ESG (Environment, Social, Government) initiatives, and aim to contribute to solving social issues through close communication with supply chain partners and stakeholders.

Progress with the Mid-Term Management Plan (in Fiscal 2024)

In fiscal 2024, the Company received from the U.S. Food and Drug Administration (FDA) a complete response letter (CRL) concerning SI-6603, and approval for SI-6603 was not obtained. Although the Company aims to resubmit an application for SI-6603 within a year of receipt of the CRL, it will be difficult to release SI-6603 during the period of the current mid-term management plan, and achieving the numerical target (net sales of ¥40.0 billion, operating income of ¥7.0 billion) has become difficult.

Other measures the Company is implementing to cultivate the capabilities necessary for a constant growth trajectory progressed largely according to plan. The Company will continue to diligently implement the key measures in the plan.

The status of progress with the mid-term management plan in fiscal 2024 is described below.

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

-- Topline results indicating statistically significant improvement in the primary endpoint obtained in an additional Phase III clinical study in the U.S. (May 2023)

-- Biologics License Application (BLA) accepted for filing by the FDA (May 2024)

-- Risks and benefits of SI-6603 discussed and broad support for approval received at an Advisory Committee Meeting, an FDA examination process (January 2025)

-- CRL received from the FDA. Although no concerns relating to the clinical study results, including the efficacy and safety of SI-6603, were expressed, additional observations were made concerning the manufacturing facility and control of the drug substance (March 2025)

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

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

-- Phase III clinical studies (knee joint and hip joint) of Gel-One, a treatment for osteoarthritis, initiated in Japan (February 2025)

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

-- Proceeded with construction of an expanded production system to maintain a stable supply of ARTZ, a joint function improvement agent

-- Responded to product material specification changes for the purpose of cost structure improvement

-- Maintained a system for the collection and provision of safety information and other information about JOYCLU, a joint function improvement agent

4) Construct a global production system

-- Proceeded with manufacturing system construction at Canadian subsidiary Dalton Chemical Laboratories Inc.
5) Expand the LAL business through recombinant technologies
-- Continued gathering scientific data relating to PyroSmart NextGen (a recombinant LAL reagent) and co-authoring of academic papers with ACC
-- Increased the number of countries where Fungitell (a beta-glucan-detecting in vitro diagnostic test) is sold and entered the hospital market
-- At the milestone 50th anniversary of the founding of overseas subsidiary Associates of Cape Cod, Inc., looking ahead to the next half century, renewal of the brand identity as a solutions company that utilizes recombinant technology

In addition to these key measures, Seikagaku also considers initiatives relating to sustainability an important priority. Seikagaku has designed and implemented effective measures based on the Basic Policy on Sustainability, instituted in 2021, and the six identified sustainability issues and has expanded their scope of application to subsidiaries.

In fiscal 2024, Seikagaku implemented a reorganization for the purpose of supporting initiatives related to the material issues and realizing Seikagaku's future vision. In October 2024, the Company established the HR Strategy Department to further strengthen the response to human resources strategy-related issues and promote human capital management. The Department is responsible for developing an environment, systems, programs, and mechanisms with a view to future business development, such as cultivation of autonomous employees, reform of personnel systems, enhancement of engagement, and a succession plan.

Also, to utilize renewable energy to supply some of the power used at the Takahagi Plant, the Company installed in the Plant solar power generation equipment.

In addition, Seikagaku received the following ratings from external assessment organizations and has published them on the Seikagaku website.

・EcoVadis: Bronze Medal

・CDP (climate change evaluation) score: B

・Business classification assessment based on the Act on Rationalizing Energy Use and Shifting to Non-fossil Energy: Class S

4. Dividend Policy

As a means of ensuing sustainable profit growth and improving corporate value, Seikagaku believes in the sharing of profits with its shareholders.Management regards the return of profits to shareholders as an important priority and, while taking an annual dividend of ¥26 per share as the basis, will consider dividend increases, taking into account the trend in business performance, the financial position, and other factors. Also, while taking into consideration future business expansion and the total return ratio, Seikagaku will weigh the purchase of treasury stock when appropriate.

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

In accordance with the above dividend policy, the Company plans to pay a year-end dividend for the fiscal year ended March 31, 2025 of ¥15 per share. As a result, the annual dividend forecast is ¥30 per share, (representing a dividend payout ratio of 134.8%), including an interim dividend of ¥15 (resolved at a meeting of the Board of Directors Held on November 8, 2024). The Company plans to an annual dividend of 30 yen per share for the fiscal year ending March 31, 2026 (including an interim dividend of ¥15).

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