

May 13, 2024

SEIKAGAKU CORPORATION
Consolidated Financial Results (Japan GAAP) (Summary)
for the Fiscal 2023
(Year Ended March 31, 2024)

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 21, 2024
Date of dividend payment (Planned): June 24, 2024

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

1. Consolidated Financial Results for the Fiscal 2023(from April 1, 2023 to March 31, 2024)

(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 2023	36,213	8.2	433	(79.5)	1,691	(44.9)	2,186	(2.2)
Fiscal 2022	33,456	(4.0)	2,114	(53.0)	3,069	(43.1)	2,236	(40.1)

(Note) Comprehensive income:

Fiscal 2023: 6,469 million yen [65.0 %]
Fiscal 2022: 3,921 million yen [(14.3) %]

	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 2023	40.08	-	3.1	2.1	1.2
Fiscal 2022	40.49	-	3.3	4.1	6.3

(2) Consolidated Financial Position

	Total assets	Total equity	Equity ratio	Total equity per share
	Millions of Yen	Millions of Yen	%	Yen
Fiscal 2023	81,795	72,282	88.4	1,324.82
Fiscal 2022	75,625	67,216	88.9	1,232.41

(Reference) Shareholders' Equity:

Fiscal 2023: 72,282 million yen
Fiscal 2022: 67,216 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 2023	513	(7,209)	(1,461)	18,701
Fiscal 2022	1,574	3,365	(3,244)	25,798

2. Dividends

	Dividends per share				
	1 st Quarter	2 nd Quarter	3 rd Quarter	Fiscal Year-end	Annual
	Yen	Yen	Yen	Yen	Yen
Fiscal 2022	-	13.00	-	13.00	26.00
Fiscal 2023	-	13.00	-	13.00	26.00
Fiscal 2024 (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 2022	1,426	64.2
Fiscal 2023	1,418	64.9	2.0
Fiscal 2024 (Forecast)		47.4	

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

(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 2024	40,000	10.5	3,950	812.1	4,550	169.0	3,450	(57.8)

* 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: No
- (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, 2024	56,814,093 shares	As of March 31, 2023	56,814,093 shares
As of March 31, 2024	2,253,745 shares	As of March 31, 2023	2,273,029 shares
Fiscal 2023	54,554,782 shares	Fiscal 2022	55,239,983 shares

(Reference) Non-Consolidated Financial Results
Non-Consolidated Financial Results for Fiscal 2023 (from April 1, 2023 to March 31, 2024)

(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 2023	25,141	13.8	(332)	-	1,804	(2.2)	2,537	41.1
Fiscal 2022	22,091	(12.3)	0	(100.0)	1,845	(50.2)	1,798	(28.0)

	Net income per share	Diluted net income per share
	Yen	Yen
Fiscal 2023	46.50	-
Fiscal 2022	32.55	-

(2) Non-Consolidated Financial Position

	Total assets	Total Equity	Equity ratio	Total Equity per share
	Millions of Yen	Millions of Yen	%	Yen
Fiscal 2023	66,686	60,314	90.4	1,105.46
Fiscal 2022	63,068	56,672	89.9	1,039.07

(Reference) Shareholders' Equity:

Fiscal 2023: 60,314 million yen

Fiscal 2022: 56,672 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, 2024 (fiscal 2023), net sales were ¥36,213 million, up 8.2% year on year. The increase is attributable to sales volume growth from domestic pharmaceuticals and from ARTZ for China and other overseas pharmaceuticals, coupled with an increase in royalty income, which offset lower sales volume of Gel-One, an intra-articular single-injection viscosupplement for the treatment of knee osteoarthritis for the U.S. market, and a decline in overseas sales in the LAL business.

Operating income fell 79.5% year on year to ¥433 million, a decline mainly attributable to an increase in the cost of sales ratio due to an inventory write-down, bringing forward of facilities maintenance to strengthen the production system, and higher expenses in the LAL business. Ordinary income fell 44.9% year on year to ¥1,691 million, while net income attributable to owners of parent fell 2.2% to ¥2,186 million.

1) Net sales by segment

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.

Pharmaceutical Business

- Domestic Pharmaceuticals (¥12,100 million, up 7.3% year on year)

Revenue from domestic pharmaceuticals rose 7.3% year on year, mainly due to increases in the Company’s 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 increased year on year thanks to continued switching from competing products. This growth led to an increase in the Company’s sales, despite the impact of National Health Insurance (NHI) drug price reductions.

Deliveries to medical institutions of the OPEGAN series increased year on year, reflecting a continued gradual market growth trend accompanying population aging. This brought an increase in the Company’s sales, despite the impact of NHI drug price reductions.

In the results for other products, the Company’s sales of MucoUp, a submucosal injection agent for endoscopic surgery, increased, reflecting a sales partner inventory adjustment. The Company’s sales of HERNICORE, a treatment for lumbar disc herniation, remained at the prior-year level.

Also, the Company’s sales of the joint function improvement agent JOYCLU declined year on year. 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 (¥10,059 million, up 17.9% year on year)

Revenue from overseas pharmaceuticals rose 17.9% year on year thanks mainly to increases in the Company’s sales of ARTZ for China and SUPARTZ FX, an intra-articular 5-injection viscosupplement for the treatment of knee osteoarthritis for the U.S. market, despite lower sales of Gel-One, an intra-articular single-injection viscosupplement for the treatment of knee osteoarthritis for the U.S. market.

Local sales volume and the Company’s sales of Gel-One declined year on year, despite a gradual trend toward recovery from the impact of an insurance reimbursement system change implemented in July 2022.

Local sales volume in the U.S. of SUPARTZ FX rose due to increased preference for a stable product subject to minimal price fluctuation against the backdrop of an insurance reimbursement system change. The Company’s sales rose because of the combined impact of a shipping schedule adjustment and yen depreciation.

Local sales volume of ARTZ for China rose, reflecting recovery in the patient consultation rate as the impact of

COVID-19 dissipated. In addition, the Company's sales rose sharply year on year, reflecting a rebound following lower-than-normal sales in the first quarter of fiscal 2022 when a packaging material change led to an absence of shipments and the bringing forward of product shipments originally scheduled for fiscal 2024.

- Bulk Products and Contract Development and Manufacturing Organization (¥3,083 million, up 5.7% year on year)

Sales increased due to higher sales of contract development and manufacturing and other services of overseas subsidiary Dalton Chemical Laboratories, Inc. coupled with yen depreciation.

As a result of these developments and an increase in royalty income (¥699 million, -), sales from the Pharmaceuticals business segment rose 14.2% year on year to ¥25,942 million.

LAL Business

Sales from the LAL business segment decreased 4.3% year on year to ¥10,271 million. Although sales in Japan were at the prior-year level, sales at overseas subsidiary Associates of Cape Cod, Inc. declined as special demand accompanying the spread of COVID-19 infection subsided.

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 2023 were ¥7,484 million, or 21.1% of net sales (excluding royalties), and the number of R&D personnel was 195, or 19.7% of the total number of employees, at March 31, 2024.

The status of progress of principal R&D activities is described below.

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

Follow-up observation in an additional Phase III clinical study was completed in March 2023, and topline results indicating statistically significant improvement in the primary endpoint were obtained in May. Preparations are currently underway to obtain approval.

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.

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.

Seikagaku is considering the policy on future development based on the data obtained.

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 will consider the future direction for development in the U.S., China, and South Korea while assessing progress with identification of the cause of shock or anaphylaxis of JOYCLE.

SI-613-ETP

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

SI-613 is a formulation in which hyaluronic acid and diclofenac (an anti-inflammatory agent) are chemically bound using Seikagaku's own proprietary technology. It is expected to improve symptoms associated with osteoarthritis and enthesopathy by releasing diclofenac by hydrolysis.

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 now proceeding with selection of a sales partner and preparations for a new drug application (NDA) at an early date.

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. There is no substantial change in the other R&D activities.

2. Forecasts for Fiscal 2024

For fiscal 2024 (April 1, 2024 to March 31, 2025), the Company forecasts consolidated net sales of ¥40,000 million, an increase of 10.5% from the previous year. The main driver of the projected revenue increase is an expected increase in royalty income. Pharmaceutical sales are projected to decline year on year due to the impact of NHI price reductions for domestic pharmaceuticals and shipment adjustments affecting certain overseas pharmaceuticals.

As for the earnings outlook, the Company forecasts operating income to rise by 812.1% year on year to ¥3,950 million, ordinary income to rise by 169.0% to ¥4,550 million, and net income attributable to owners of parent to rise by 57.8% to ¥3,450 million, mainly as a result of the expected increase in royalty income. At the same time, the Company forecasts increases in SG&A expenses and income taxes to result mainly from higher personnel expenses accompanying development and enhancement of an expanded production, systems-related expenses, and tax expenses.

The Company forecasts R&D expenses of ¥6,900 million, a decrease of 7.8% year on year, and a ratio of R&D expenses to net sales (excluding royalty income) of 19.4%.

The exchange rate assumption used in the forecast of consolidated financial results for fiscal 2024 is ¥145 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 2023)

In fiscal 2023, implementation of the five key measures in the mid-term management plan progressed largely as planned. Seikagaku will continue to diligently implement the key measures in order to develop the ability to maintain a constant growth trajectory in order to achieve the targets for the final year of the plan.

The status of progress with the mid-term management plan in fiscal 2023 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)

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)

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

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.

Concerning sustainability initiatives in fiscal 2023, Seikagaku conducted an engagement survey of all employees on the topic “Promotion of Diversity and Development of Human Resources,” one of the six material issues identified by Seikagaku. In addition, Seikagaku received the following ratings from external assessment organizations and published them on the Seikagaku website.

-- EcoVadis: Silver Medial

-- CDP (climate change evaluation) score: B

-- Fiscal 2021 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, 2024 of ¥13 per share. As a result, the annual dividend forecast is ¥26 per share, (representing a dividend payout ratio of 64.9%), including an interim dividend of ¥13 (resolved at a meeting of the Board of Directors Held on November 8, 2023). Based on our earnings forecast, the Company plans to increase the dividend by 4 yen to an annual dividend of 30 yen per share for the fiscal year ending March 31, 2025 (including an interim dividend of ¥15).

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