May 12, 2023

SEIKAGAKU CORPORATION

Consolidated Financial Results (Japan GAAP) (Summary) for the Fiscal 2022 (Year Ended March 31, 2023)

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, 2023
Date of dividend payment (Planned): June 21, 2023

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

1. Consolidated Financial Results for the Fiscal 2022(from April 1, 2022 to March 31, 2023)

(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 2022	33,456	(4.0)	2,114	(53.0)	3,069	(43.1)	2,236	(40.1)
Fiscal 2021	34,851	25.7	4,495	99.9	5,395	78.4	3,733	(12.4)

(Note) Comprehensive income:
Fiscal 2022: 3,921 million yen[(14.3) %]
Fiscal 2021: 4,573 million yen[(10.7) %]

	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 2022	40.49	-	3.3	4.1	6.3
Fiscal 2021	66.32	-	5.7	7.4	12.9

(2) Consolidated Financial Position

	Total assets	Total equity	Equity ratio	Total equity per share
	Millions of Yen	Millions of Yen	%	Yen
Fiscal 2022	75,625	67,216	88.9	1,232.41
Fiscal 2021	75,244	66,340	88.2	1,179.46

(Reference) Shareholders' Equity:
Fiscal 2022: 67,216 million yen
Fiscal 2021: 66,340 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 2022	1,574	3,365	(3,244)	25,798
Fiscal 2021	8,192	870	(2,151)	23,367

2. Dividends

	Dividends per share				
	1st Quarter	2nd Quarter	3rd Quarter	Fiscal Year-end	Annual
	Yen	Yen	Yen	Yen	Yen
Fiscal 2021	-	15.00	-	15.00	30.00
Fiscal 2022	-	13.00	-	13.00	26.00
Fiscal 2023 (Forecast)	-	13.00	-	13.00	26.00

	Total dividend payments (Annual)	Dividend payout ratio (Consolidated)	Dividends as a percentage of total equity (Consolidated)
	Millions of Yen	%	%
Fiscal 2021	1,687	45.2	2.6
Fiscal 2022	1,426	64.2	2.2
Fiscal 2023 (Forecast)		97.8	

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

(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 2023	32,550	(2.7)	100	(95.3)	1,550	(49.5)	1,450	(35.2)	26.59

* 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)	As of March 31, 2023	56,814,093 shares	As of March 31, 2022	56,814,093 shares
(b) Number of treasury stock at the end of the period	As of March 31, 2023	2,273,029 shares	As of March 31, 2022	567,822 shares
(c) Average number of shares issued during the period	Fiscal 2022	55,239,983 shares	Fiscal 2021	56,299,803 shares

(Reference) Non-Consolidated Financial Results

Non-Consolidated Financial Results for Fiscal 2022 (from April 1, 2022 to March 31, 2023)

(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 2022	22,091	(12.3)	0	(100.0)	1,845	(50.2)	1,798	(28.0)
Fiscal 2021	25,178	19.6	2,273	73.3	3,703	87.4	2,496	(28.5)

	Net income per share	Diluted net income per share
	Yen	Yen
Fiscal 2022	32.55	-
Fiscal 2021	44.34	-

(2) Non-Consolidated Financial Position

	Total assets	Total Equity	Equity ratio	Total Equity per share
	Millions of Yen	Millions of Yen	%	Yen
Fiscal 2022	63,068	56,672	89.9	1,039.07
Fiscal 2021	64,644	58,010	89.7	1,031.37

(Reference) Shareholders' Equity:

Fiscal 2022: 56,672 million yen

Fiscal 2021: 58,010 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, 2023 (fiscal 2022), net sales were ¥33,456 million, down 4.0% year on year. The result is attributable to a substantial decline in royalty income and a decline in sales in the pharmaceutical business due to the impact of National Health Insurance (NHI) drug price reductions in Japan, despite the positive impact of yen depreciation on the results from the LAL business and overseas pharmaceuticals.

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

1) Net sales by segment

Pharmaceutical Business

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

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

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

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

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

Although deliveries to medical institutions of HERNICORE, a treatment for lumbar disc herniation, remained at the prior-year level, the Company's sales rose due to the impact of shipment timing.

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

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

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

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

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

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

As a result of these developments and a steep decline in royalty income (¥1 million, down 100.0% year on year), sales from the Pharmaceuticals business segment fell 11.6% year on year to ¥22,723 million.

LAL Business

Sales from the LAL business segment increased 17.2% year on year to ¥10,732 million, reflecting the impact of yen depreciation on sales of reagents and diagnostics at overseas subsidiary Associates of Cape Cod, Inc. as well as steady sales in Japan.

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 2022 were ¥7,951 million, or 23.8% of net sales (excluding royalties), and the number of R&D personnel was 196, or 20.1% of the total number of employees, at March 31, 2023.

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

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

Follow-up observation in an additional Phase III clinical study was completed in March 2023, and preparations for results analysis are underway.

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.

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

Subject enrollment has been completed for a Phase III clinical study being conducted since May 2022 with the objective of evaluating efficacy and safety. After obtaining data from the clinical study currently underway, the Company plans to select a sales partner and conduct a second Phase III clinical study and a long-term study.

SI-614 is a substance produced by introducing a hydrophobic group into hyaluronic acid using Seikagaku's own proprietary technology. Ocular instillation of SI-614 in patients is expected to improve symptoms of dry eye by stabilizing the tear film and promoting corneal epithelial wound healing. Through development of SI-614, the Company aims to provide a new option for the treatment of dry eye.

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

<u>SI-613</u>

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.

<u>SI-613-ETP</u>

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.

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

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)

Subject enrollment for a pivotal study in the field of gastroenterological surgery was completed in September 2022. The study is being conducted to confirm efficacy (prevention of adhesion formation), safety, and usability in gastroenterological surgery

A pilot study in the field of gynecology was initiated in November 2021 for the purpose of expanding the scope of application of SI-449 by confirming usability and safety in gynecology.

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 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.

2. Forecasts for Fiscal 2023

For fiscal 2023, the Company forecasts net sales of ¥32,550 million, a decline of 2.7% from the previous year, to result from lower sales from overseas pharmaceuticals and the LAL business in addition to the impact of NHI drug price decreases in Japan. This would be despite a projected sales volume increase for domestic pharmaceuticals and an expected increase in royalty income.

As for the earnings outlook, the Company forecasts operating income to decline 95.3% year on year to 100 million yen due to the expected sales decrease coupled with cost increases in connection with production system expansion and soaring fuel costs. Ordinary income is projected to decline less steeply than operating income, by 49.5% to ¥1,550 million, thanks to an expected increase in non-operating income, while net income attributable to owners of parent is projected to decline by 35.2% to ¥1,450 million.

The Company forecasts R&D expenses of ¥7,200 million, a decrease of 9.5% year on year, and a ratio of R&D expenses to net sales (excluding royalty income) of 22.6%.

The exchange rate assumption used in the forecast of consolidated financial results for fiscal 2023 is ¥130 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) Background of the new mid-term management plan

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

2) Key measures

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

① **<u>Accelerate R&D utilizing unique drug-discovery technologies</u>**

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.

② **<u>Maximize the product value of SI-6603 (treatment for lumbar disc herniation)</u>**

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.

③ **<u>Maintain and enhance the business value of joint function improving agents</u>**

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 **<u>Construct a global production system</u>**

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 **<u>Expand the LAL business through recombinant technologies</u>**

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 continue to focus on these material issues, which will become 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 New Mid-Term Management Plan (in fiscal 2022)

Progress against the new mid-term management plan in fiscal 2022 is as described below.

Progress was made with "Accelerate R&D utilizing unique drug-discovery technologies," the first of five key measures set out in the management plan. Follow-up observation in a Phase III additional clinical study in the U.S. for SI-6603 (a treatment for lumbar disc herniation) was completed in March 2023, and preparations for results analysis are underway. Also, there was steady advancement in the development pipelines for SI-449 (an adhesion barrier) and SI-614 (a treatment for dry eye), as indicated by completion of subject enrollment for a pivotal clinical study in Japan of SI-449 in September 2022 and for a Phase III clinical study in the U.S. for SI-614 in February 2023. Seikagaku will continue efforts to achieve the development objectives for each pipeline.

To achieve the second key measure, "Maximize the product value of SI-6603 (treatment for lumbar disc herniation)," Seikagaku will aim to accelerate U.S. Food and Drug Administration (FDA) approval by ensuring smooth communications with the FDA utilizing Canadian subsidiary SEIKAGAKU NORTH AMERICA CORPORATION while conducting the abovementioned clinical study.

Initiatives to implement the third key measure, "Maintain and enhance the business value of joint function improving agents," include building an expanded production system for the purpose of maintaining a stable supply of ARTZ (a joint function improvement agent) and measures underway for the early realization of product material specification changes aimed at cost structure improvement. Seikagaku also continues to gather and provide safety information on the joint function improving agent JOYCLU and is conducting clinical research to promptly identify the cause of side effects.

Seikagaku is proceeding with arrangements to make Dalton and the Takahagi Plant dual production bases in order to "Construct a global production system," the fourth key measure in the management plan. Construction of a production system at Canadian subsidiary Dalton Chemical Laboratories, Inc. is under consideration.

With regard to "Expand the LAL business through recombinant technologies," the fifth key measure, Seikagaku continues to accumulate scientific data relating to PyroSmart NextGen® recombinant LAL reagent and is implementing measures to achieve market penetration for this product, such as co-authoring of academic papers with overseas subsidiary Associates of Cape Cod, Inc. Another objective is to expand the market for Fungitell, an in-vitro diagnostic reagent, by increasing the number of countries where the product is sold and further accelerating new expansion into the hospital market.

Each of the key measures in the mid-term management plan progressed mostly according to plan in fiscal 2022. Seikagaku will continue to assiduously implement the key measures to ensure that the Group maintains a constant growth trajectory in order to achieve the targets set out for the final year of the plan.

Seikagaku also considers initiatives relating to sustainability an important priority and has designed and implemented effective measures based on the Basic Policy on Sustainability instituted in 2021 and the six identified sustainability issues and expanded their scope of application to subsidiaries. In January 2023, Seikagaku established the Supply Chain Management Department with the aim of helping solve social problems by practicing sustainable raw materials procurement and providing a stable supply of products in cooperation with suppliers. To address one of the environmental issues, Seikagaku has revised upwards its CO2 emissions reduction target and is implementing measures to achieve the new target. Going forward, in addition to these measures, Seikagaku will promote initiatives to address sustainability-related issues in areas including respect for human rights, consideration of the working environment for employees, fair and appropriate trading with business partners, and enhancement of corporate governance and will proactively disclose information to ensure sufficient communication with stakeholders.

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, 2023 of ¥13 per share. As a result, the annual dividend forecast is ¥26 per share, (representing a dividend payout ratio of 64.2%), including an interim dividend of ¥13 (resolved at a meeting of the Board of Directors Held on November 8, 2022). The Company plans to pay an annual dividend of ¥26 per share for the fiscal year ending March 31, 2024 (including an interim dividend of ¥13).

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