August 4, 2023

SEIKAGAKU CORPORATION
Consolidated Financial Results (Japan GAAP) (Summary) for the First Three Months of Fiscal 2023 (Three-Month Period Ended June 30, 2023)

Listed exchanges: Tokyo Stock Exchange (Prime Market)
Stock code number: 4548
URL: https://www.seikagaku.co.jp/en/

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

1. Consolidated Financial Results for the First Three Months of Fiscal 2023 (from April 1, 2023 to June 30, 2023)

(1) Consolidated Financial Results

(Percentages indicate changes from the same period in the previous fiscal year)

	Net sales		Operating income		Ordinary income	
	Millions of Yen	%	Millions of Yen	%	Millions of Yen	%
First three months of fiscal 2023	9,661	16.3	1,298	15.3	1,959	14.3
First three months of fiscal 2022	8,307	(29.5)	1,126	(74.7)	1,714	(62.8)

	Net income attributable to owners of parent		Net income per share	Diluted net income per share
	Millions of Yen	%	Yen	Yen
First three months of fiscal 2023	1,887	26.4	34.62	-
First three months of fiscal 2022	1,493	(59.1)	26.62	-

(Note) Comprehensive income:
First three months of fiscal 2023: 3,048 million yen [41.0%]
First three months of fiscal 2022: 2,162 million yen [(54.7)%]

(2) Consolidated Financial Position

	Total assets	Total equity	Equity ratio
	Millions of Yen	Millions of Yen	%
As of June 30, 2023	77,067	69,555	90.3
As of March 31, 2023	75,625	67,216	88.9

(Reference) Shareholders' equity:
As of June 30, 2023: 69,555 million yen
As of March 31, 2023: 67,216 million yen

2. Dividends

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

(Note) Revision of the forecasts most recently announced: No

*** Notes**

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

(2) Application of specific accounting methods for preparing the quarterly consolidated financial statements: Yes

(3) Changes in accounting policies, changes in accounting estimates, and retrospective restatements

(a) Changes in accounting policies 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

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

(a)Number of shares at the end of the period (including treasury stock)	As of June 30, 2023	56,814,093 shares	As of March 31, 2023	56,814,093 shares
(b) Number of treasury stock at the end of the period	As of June 30, 2023	2,273,029 shares	As of March 31, 2023	2,273,029 shares
(c) Average number of shares issued during the period (three months)	First three months of fiscal 2023	54,541,064 shares	First three months of fiscal 2022	56,105055 shares

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

*** Disclaimer regarding forward-looking information including appropriate use of forecasted financial results**

At this time it would be difficult to reasonably assess a forecast of consolidated financial results for the fiscal year ending March 31, 2024.

1. Results of Operations for the First Quarter of Fiscal 2023 (Three-Month Period Ended June 30, 2023)

(1) Qualitative explanation on quarterly financial results

In the first three months (April 1 to June 30, 2023) of the fiscal year ending March 31, 2024 (fiscal 2023), net sales were ¥9,661 million, up 16.3% year on year. The increase is attributable to an increase in royalty income coupled with year-on-year sales volume growth for ARTZ in China and domestic pharmaceuticals, which offset a decline in overseas sales in the LAL business and lower sales volume of Gel-One, an intra-articular single-injection viscosupplement for the treatment of knee osteoarthritis.

Operating income rose 15.3% year on year to ¥1,298 million. Operating income growth lagged behind revenue growth because of higher SGA expenses at overseas subsidiaries. Ordinary income and net income attributable to owners of parent rose 14.3% to ¥1,959 million and 26.4% to ¥1887 million, respectively.

1) Net sales by segment

Pharmaceutical Business

- Domestic Pharmaceuticals (¥3,312 million, up 11.7% 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 rose due to an increase in shipment volume, despite the impact of NHI drug price reductions.

The Company's sales of the joint function improvement agent JOYCLU declined year on year because of a shipping schedule adjustment. 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 proactively gather side effects reports and other information and provide safety-related information. The Company also conducted clinical research to identify the cause of side effects with the cooperation of specialists and medical institutions and will continue to analyze data obtained through this research and consider proposals that will lead to correct use.

Deliveries to medical institutions of the OPEGAN series of ophthalmic viscoelastic devices increased year on year due to a market growth trend accompanying population aging as well as the impact of limited shipments of competing products. The Company's sales rose sharply on higher shipment volume, despite the impact of NHI drug price reductions.

The Company's sales of MucoUp, a submucosal injection agent for endoscopic surgery, decreased, reflecting a sales partner inventory adjustment.

Deliveries to medical institutions and the Company's sales of HERNICORE, a treatment for lumbar disc herniation, remained at the prior-year level.

- Overseas Pharmaceuticals (¥2,324 million, up 30.0% year on year)

Local sales volume in the U.S. and the Company's sales 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 relating to price disclosure implemented in July 2022.

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

Local sales volume in China of ARTZ rose, reflecting a rebound in the patient consultation rate following a decline in the first quarter of the previous fiscal year due to lockdowns in major cities accompanying the renewed spread of COVID-19. The Company's sales rose sharply year on year because there were no shipments in the prior-year first quarter due to a packaging material change.

- Bulk Products and Contract Development and Manufacturing Organization (¥835 million, up 14.0% year on year)

Sales increased due to growth from bulk products and the positive impact of yen depreciation on contract

development and manufacturing and other services of overseas subsidiary Dalton Chemical Laboratories, Inc.

As a result of these developments and an increase in royalty income (¥699 million, -), sales from the Pharmaceuticals business segment rose 30.7% year on year to ¥7,172 million.

LAL Business

Although sales in Japan were at the prior-year level, sales from the LAL business segment decreased 11.7% year on year to ¥2,488 million as special demand accompanying the spread of COVID-19 infection subsided, despite the positive impact of yen depreciation on the results of overseas subsidiary Associates of Cape Cod, Inc.

(2) Explanation of forward-looking information, including the forecast of consolidated financial results

Although the Company has already achieved the full-year income forecasts announced on May 12, 2023, in light of expected lower revenue from overseas pharmaceuticals and the LAL business and anticipated expenses in preparation for an application for approval of SI-6603, there is no change in the forecast of consolidated financial results.

Note: The exchange rate assumption to be used in the forecast of consolidated financial results for the second quarter onward is ¥130 to the U.S. dollar.

(3) 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.

To achieve early and continuous launching of new products, which hold the key to future business growth, the Group will engage in efficient R&D activities focused on target compounds and high-priority target diseases and make efforts to increase the number of projects through reinforcement of unique drug-discovery technologies and utilization of open innovation.

Total R&D expenses in the first three months of fiscal 2023 were ¥1,738 million, or 19.4% of net sales (excluding royalties).

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.

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.)

Follow-up observation in a Phase III clinical study conducted for the purpose of evaluating efficacy and safety was completed in June 2023, and the Company is currently analyzing the data obtained from the 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.

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. Seikagaku plans to proceed with an application for approval of SI-449 following detailed analysis of data obtained in the two studies and sales partner selection.
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 on the other R&D activities.

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