November 8, 2023

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

Listed exchanges: Tokyo Stock Exchange (Prime Market)
Stock code number: 4548
URL: https://www.seikagaku.co.jp/en/
Scheduled date to commence dividend payment: December 4, 2023

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

1. Consolidated Financial Results for the First Six Months of Fiscal 2023 (from April 1, 2023 to September 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 six months of fiscal 2023	18,061	4.7	1,482	(43.2)	2,327	(35.4)
First six months of fiscal 2022	17,258	(15.9)	2,610	(56.8)	3,600	(43.7)

	Net income attributable to owners of parent		Net income per share	Diluted net income per share
	Millions of Yen	%	Yen	Yen
First six months of fiscal 2023	2,102	(33.1)	38.54	-
First six months of fiscal 2022	3,141	(37.4)	56.32	-

(Note) Comprehensive income:
First six months of fiscal 2023: 5,021 million yen [(2.9)%]
First six months of fiscal 2022: 5,173 million yen [(16.7)%]

(2) Consolidated Financial Position

	Total assets	Total equity	Equity ratio
	Millions of Yen	Millions of Yen	%
As of September 30, 2023	79,620	71,544	89.9
As of March 31, 2023	75,625	67,216	88.9

(Reference) Shareholders' equity:
As of September 30, 2023: 71,544 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	-	13.00			
Fiscal 2023 (Forecast)			-	13.00	26.00

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

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

(Percentages indicate changes from the previous 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	36,100	(7.9)	1,300	(38.5)	2,250	(26.7)	2,600	(16.2)	47.66

(Note) Revision of the forecasts most recently announced: Yes

* 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 September 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 September 30, 2023	2,253,631 shares	As of March 31, 2023	2,273,029 shares
(c) Average number of shares issued during the period (six months)	First six months of fiscal 2023	54,549,160 shares	First six months of fiscal 2022	55,783,570 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**

The forecast shown in these materials are based on information currently available and certain assumptions that the Company regards as reasonable. Actual performance and other results may differ materially from these forecasted figures due to various factors.

1. Results of Operations for the First Six Months of Fiscal 2023

(Six-Month Period Ended September 30, 2023)

(1) Qualitative explanation on quarterly financial results

In the first six months (April 1 to September 30, 2023) of the fiscal year ending March 31, 2024 (fiscal 2023), net sales were ¥18,061 million, up 4.7% year on year. The increase is attributable to year-on-year sales volume growth for domestic pharmaceuticals and China of ARTZ coupled with an increase in royalty income, 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 fell 43.2% year on year to ¥1,482 million, despite the revenue increase, due to an increase in the cost of sales ratio and higher SGA expenses at overseas subsidiaries. Ordinary income and net income attributable to owners of parent fell 35.4% to ¥2,327 million and 33.1% to ¥2,102 million, respectively.

1) Net sales by segment

Pharmaceuticals Business

- Domestic Pharmaceuticals (¥6,402 million, up 10.2% 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 National Health Insurance (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 analyze data obtained through this research and continuously 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 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, increased, reflecting a sales partner inventory adjustment.

Deliveries to medical institutions and the Company's sales of HERNICORE, a treatment for lumbar disc herniation, decreased year on year.

- Overseas Pharmaceuticals (¥4,367 million, down 0.4% 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 an insurance reimbursement system change 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 the insurance reimbursement 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 half 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 (¥1,622 million, up 8.3% 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 12.0% year on year to ¥13,091 million.

LAL Business

Sales from the LAL business segment decreased 10.7% year on year to ¥4,970 million on lower sales in Japan and overseas, with sales in Japan declining due to non-recurrence of a large equipment sale recorded in the prior-year first half and overseas sales declining as special demand accompanying the spread of COVID-19 infection subsided at overseas subsidiary Associates of Cape Cod, Inc.

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

Taking into account the business results for the first six months and factors foreseeable at this time, the Company has revised the forecast of consolidated financial results for the fiscal year ending March 31, 2024 (April 1, 2023 to March 31, 2024) announced on May 12, 2023, as detailed below.

Net sales are projected to exceed the previously announced forecast due to growth from both ARTZ in China and domestic pharmaceuticals combined with the positive effect of yen depreciation, despite a greater-than-expected decline in overseas sales in the LAL business.

With regard to earnings, operating income, ordinary income, and net income attributable to owners of parent are expected to exceed the previous forecasts, with the projected increase in revenue compensating for greater-than-expected increases in R&D expenses and SGA expenses at overseas subsidiaries accompanying yen depreciation. The Company forecasts R&D expenses of ¥7,550 million (¥350 million above the previous forecast of ¥7,200 million) and a ratio of R&D expenses to net sales (excluding royalty income) of 21.3%.

Note:

1. The exchange rate assumption used for the forecast of consolidated financial results for the third quarter onward has been changed from ¥130 to ¥145 to the U.S. dollar.
2. Although operating income and ordinary income achieved the full-year consolidated earnings forecast in the second quarter, we anticipate that costs associated with the application for approval of SI-6603, a treatment for lumbar disc herniation, will be concentrated in the third quarter and beyond.

(Millions of yen)

	Net sales	Operating income	Ordinary income	Net income attributable to owners of parent	Net income per share
Previous forecast (A)	32,550	100	1,550	1,450	26.59
Revised forecast (B)	36,100	1,300	2,250	2,600	47.66
Change (B - A)	3,550	1,200	700	1,150	-
Change (%)	10.9	-	45.2	79.3	-
Reference: Results for fiscal 2022	33,456	2,114	3,069	2,236	40.49

Notes: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) 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 six months of fiscal 2023 were ¥3,410 million, or 19.6% 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. Preparations are currently underway for a Biologics License Application (BLA) to US FDA at an early date.

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. In light of this outcome, the Company will consider the future development policy while proceeding with analysis of the data obtained.

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 in the other R&D activities.

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

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