November 8, 2022

SEIKAGAKU CORPORATION
Consolidated Financial Results (Japan GAAP) (Summary) for the First Six Months of Fiscal 2022 (Six-Month Period Ended September 30, 2022)

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 2, 2022

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

1. Consolidated Financial Results for the First Six Months of Fiscal 2022 (from April 1, 2022 to September 30, 2022)

(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 2022	17,258	(15.9)	2,610	(56.8)	3,600	(43.7)
First six months of fiscal 2021	20,530	54.6	6,038	665.0	6,393	492.9

	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 2022	3,141	(37.4)	56.32	-
First six months of fiscal 2021	5,019	422.2	89.07	-

(Note) Comprehensive income:
First six months of fiscal 2022: 5,173 million yen [(16.7)%]
First six months of fiscal 2021: 6,208 million yen [315.5%]

(2) Consolidated Financial Position

	Total assets	Total equity	Equity ratio
	Millions of Yen	Millions of Yen	%
As of September 30, 2022	77,823	69,753	89.6
As of March 31, 2022	75,244	66,340	88.2

(Reference) Shareholders' equity:
As of September 30, 2022: 69,753 million yen
As of March 31, 2022: 66,340 million yen

2. Dividends

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

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

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

(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 2022	33,500	(3.9)	1,700	(62.2)	2,900	(46.2)	2,650	(29.0)	48.12

(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: Yes
(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, 2022	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 September 30, 2022	1,655,104 shares	As of March 31, 2022	567,822 shares
(c) Average number of shares issued during the period (six months)	First six months of fiscal 2022	55,783,570 shares	First six months of fiscal 2021	56,353,031 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 2022
(Six-Month Period Ended September 30, 2022)
(1) Qualitative explanation on quarterly financial results

In the first six months (April 1 to September 30, 2022) of the fiscal year ending March 31, 2023 (fiscal 2022), net sales were ¥17,258 million, down 15.9% year on year. Growth in the LAL business was offset by declining sales in the pharmaceutical business due to a substantial decline in royalty income and the impact of National Health Insurance (NHI) drug price reductions in Japan.

Operating income fell 56.8% year on year to ¥2,610 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 43.7% to ¥3,600 million and 37.4% to ¥3,141 million, respectively, declining less steeply than operating income because of factors including the recording of foreign exchange gains due to yen depreciation.

1) Net sales by segment
Pharmaceuticals Business
- Domestic Pharmaceuticals (¥5,808 million, down 14.7% year on year)

Deliveries to medical institutions of ARTZ, a joint function improvement agent for knee osteoarthritis, increased year on year amid signs that the market is recovering from the impact of COVID-19, 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 resulting from the shipment schedule.

The Company's sales of the joint function improvement agent JOYCLU, launched on May 19, 2021, declined substantially year on year, reflecting concentration of shipments in the first six months of fiscal 2021. Although the Company called attention to the risk of shock or anaphylaxis in the Important Side Effects section of the JOYCLU package insert, in response to multiple reports of shock or anaphylaxis occurring in patients following administration of JOYCLU, the Company issued a Dear Healthcare Professionals Letter of Rapid Safety Communication (Blue Letter) on June 1, 2021 to increase awareness of these side effects among healthcare professionals. The Company 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 the 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, with the impact of COVID-19 running its course and the market gradually returning to the pre-COVID growth trend. The Company's sales fell as a result of NHI drug price reductions coupled with an inventory adjustment by the sales partner.

The Company's sales of MucoUp, a submucosal injection agent for endoscopic surgery, decreased, reflecting a decline in shipments from a high level in the first half of the previous fiscal year and 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 as a result of the shipment schedule.

- Overseas Pharmaceuticals (¥4,384 million, down 1.5% 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 relating to price disclosure 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, was at the prior-year level, reflecting continuation of unfavorable market conditions for multiple-injection products due to the trend toward preference for products that require fewer injections. The Company's sales fell as a result of shipment timing.

Local sales volume in China of ARTZ fell sharply amid continuing lockdowns in major cities accompanying the renewed spread of COVID-19. The Company's sales declined substantially because there were no shipments in the first quarter due to a packaging material change. Shipments restarted in August 2022 in accordance with the annual shipment plan.

- Bulk Products and Contract Development and Manufacturing Organization (¥1,497 million, up 12.6% year on year)

Although sales of bulk products were at the prior-year level, sales of contract development and manufacturing and other services of overseas subsidiary Dalton Chemical Laboratories, Inc. rose due to the impact of yen depreciation.

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 27.5% year on year to ¥11,692 million.

LAL Business

Sales from the LAL business segment increased 26.7% year on year to ¥5,566 million, reflecting steady sales in Japan and the contribution from higher sales of Bacterial Endotoxin Testing (BET) reagents and Clinical Diagnostic (Fungitell) reagents and higher orders for contract testing services attributable to reinforcement of sales activities at overseas subsidiary Associates of Cape Cod, Inc.

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

The Company previously refrained from announcing the forecasts of consolidated financial results for the fiscal year ending March 31, 2023 (fiscal 2022) because it was difficult to prepare reasonable earnings forecasts due to the need to assess the progress of efforts currently underway to identify the cause of the occurrence of shock or anaphylaxis associated with the joint function improvement agent JOYCLU. The Company hereby announces the forecasts of consolidated financial results for fiscal 2022, prepared on the basis of the state of progress at the current point in time, forecasts, and other information.

For fiscal 2022, the Company forecasts net sales of ¥33,500 million, a decrease of 3.9% from the previous fiscal year to result from a sharp decline in royalty income and substantial impact from NHI price reductions in Japan. These factors are projected to offset the positive effects of higher sales volumes of pharmaceuticals in Japan and the impact of yen depreciation on overseas pharmaceutical sales.

The Company forecasts operating income of ¥1,700 million, a decrease of 62.2% year on year to result from the expected sales decrease and higher expenses at overseas subsidiaries, including foreign currency translation, despite a projected 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 are expected to decline less steeply than operating income because of expected foreign exchange gains related to valuation of foreign currency-denominated assets. The Company forecasts a 46.2% decrease in ordinary income to ¥2,900 million and a 29.0% decrease in net income attributable to owners of the parent to ¥2,650 million.

Although the Company achieved the full-year income forecasts in the second quarter, the above forecasts reflect an expected decrease in sales of contract testing services at an overseas subsidiary, anticipated higher expenses to result from concentration of R&D expenses in the third quarter and beyond, soaring fuel costs, and concentration in the third quarter and beyond of periodic plant maintenance, originally scheduled to be performed by the second quarter, because of a semiconductor shortage and other factors.

The Company forecasts R&D expenses of ¥8,000 million, a decrease of 11.2% year on year, and a ratio of R&D expenses to net sales (excluding royalty income) of 23.9%.

Note: The exchange rate assumption used in the forecast of consolidated financial results for fiscal 2022 is ¥140 to the U.S. dollar for 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)	-	-	-	-	-
Revised forecast (B)	33,500	1,700	2,900	2,650	48.12
Change (B - A)	-	-	-	-	-
Change (%)	-	-	-	-	-
Reference: Results for fiscal 2021	34,851	4,495	5,395	3,733	66.32

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.

The Company will promptly announce a mid-term management plan once it becomes possible to reasonably formulate a plan.

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 2022 were ¥3,407 million, or 19.7% of net sales (excluding royalties).

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

SI-449 (adhesion barrier: developed in Japan)

Although a delay occurred in the clinical trial schedule of a pivotal study of SI-449 in the field of gastroenterological surgery due to the spread of COVID-19 infection, subject enrollment was completed in September. The study is being conducted for the purpose of confirming efficacy (prevention of adhesion formation), safety, and usability in gastroenterological surgery.

Subject enrollment in a pilot study being conducted being conducted in the field of gynecology for the purpose of expanding the scope of application of SI-449 was completed in May 2022. Following the observation periods of both studies, the Company will focus for a new product application based on the data obtained.

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.

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