

SEIKAGAKU CORPORATION
Consolidated Financial Results (Japan GAAP) (Summary)
for the First Six Months of Fiscal 2020
(Six-Month Period Ended September 30, 2020)

Listed exchanges: Tokyo Stock Exchange (First Section)

Stock code number: 4548

URL: <https://www.seikagaku.co.jp/en/>

Scheduled date to commence dividend payment: December 2, 2020

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

1. Consolidated Financial Results for the First Six Months of Fiscal 2020
(from April 1, 2020 to September 30, 2020)

(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 2020	13,533	(13.0)	718	(66.6)	1,098	(55.6)
First six months of fiscal 2019	15,555	9.1	2,150	123.1	2,471	(0.2)

	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 2020	976	(-)	17.30	-
First six months of fiscal 2019	(10,766)	(-)	(190.86)	-

(Note) Comprehensive income:

First six months of fiscal 2020: 1,509 million yen [- %]

First six months of fiscal 2019: (10,958) million yen [- %]

(2) Consolidated Financial Position

	Total assets	Total equity	Equity ratio
	Millions of Yen	Millions of Yen	%
As of September 30, 2020	66,981	60,483	90.3
As of March 31, 2020	68,501	59,767	87.2

(Reference) Shareholders' equity:

As of September 30, 2020: 60,483 million yen

As of March 31, 2020: 59,767 million yen

2. Dividends

	Dividends per share				
	1st Quarter	2nd Quarter	3rd Quarter	Year-end	Annual
	Yen	Yen	Yen	Yen	Yen
Fiscal 2019	-	13.00	-	13.00	26.00
Fiscal 2020	-	10.00	-	-	-
Fiscal 2020 (Forecast)	-	-	-	10.00	20.00

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

3. Forecast of Consolidated Financial Results for Fiscal 2020 (from April 1, 2020 to March 31, 2021)

(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 2020	26,650	(7.0)	550	(71.9)	1,400	(64.8)	1,150	-	20.38

(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 September 30, 2020	56,814,093 shares	As of March 31, 2020	56,814,093 shares
(b) Number of treasury stock at the end of the period	As of September 30, 2020	384,371 shares	As of March 31, 2020	397,767 shares
(c) Average number of shares issued during the period (six months)	First six months of fiscal 2020	56,421,925 shares	First six months of fiscal 2019	56,409,157 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 2020

(Six-Month Period Ended September 30, 2020)

(1) Qualitative explanation on quarterly financial results

In the first six months (April 1 to September 30, 2020) of the fiscal year ending March 31, 2021 (fiscal 2020), net sales were ¥13,533 million, down 13.0% year on year. The result is attributable to a decrease in revenue from the pharmaceuticals business due to the impact of National Health Insurance (NHI) drug price reductions in Japan coupled with a decrease in outpatient services accompanying the spread of COVID-19 infection, despite the positive impact on revenue of the consolidation of Dalton Chemical Laboratories, Inc. as a wholly owned subsidiary in March 2020.

Operating income fell 66.6% year on year to ¥718 million as a result of the sales decrease and an increase in R&D expenses attributable to costs related to an additional clinical study underway in the U.S. for SI-6603, a treatment for lumbar disc herniation. This occurred despite lower operating expenses, which reflected factors including a decrease in depreciation due to non-recurrence of an impairment loss recognized in the same period of the previous fiscal year and a review of sales promotion expenses. Ordinary income fell 55.6% year on year to ¥1,098 million, reflecting the decline in operating income, despite positive factors that included the recording of royalty income, and a recovery of net income attributable to owners of parent to ¥976 million. It turned positive following a net loss of ¥10,766 million in the same period of the previous fiscal year incurred due to recognition of an impairment loss on property, plant and equipment related to the pharmaceuticals business.

1) Net sales by segment

Pharmaceutical Business

- Domestic Pharmaceuticals (¥6,278 million, down 13.5% year on year)

A decrease in outpatient services accompanying the spread of COVID-19 infection led to contraction of the overall market for ARTZ, a joint function improving agent for knee osteoarthritis, and lower deliveries to medical institutions. Nevertheless, the switch from competing products to ARTZ continued and market share increased, reflecting factors that included the continuing effectiveness of measures to acquire new user facilities implemented in the previous fiscal year. The market has been on a recovery trend since June, when the state of emergency declaration in Japan was lifted. The Company's sales fell, due in part to the impact of NHI drug price reductions.

Although the overall market for the OPEGAN series of ophthalmic viscoelastic devices contracted amid a decrease in the number of cataract surgeries accompanying the priority placed on COVID-19 infection, deliveries to medical institutions increased due to the impact of shipment adjustments for competing products. The Company's sales also increased as the higher volume compensated for the impact of NHI drug price revisions.

The Company's sales of MucoUp, a submucosal injection agent for endoscopic surgery, fell year on year, reflecting the impact of a sales offensive involving a low-price strategy for a competing product coupled with a decrease in the number of endoscopic surgeries accompanying the spread of COVID-19 infection.

Deliveries to medical institutions of HERNICORE, a treatment for lumbar disc herniation, increased due to steady growth in the number of new user facilities, despite the impact of a decrease in outpatient services accompanying the spread of COVID-19 infection. The Company's sales fell, reflecting a high level of shipments in the same period of the previous fiscal year. To provide the opportunity for treatment to greater numbers of patients, the Company is continuing efforts to provide information and collect post-marketing safety data to ensure appropriate use and safety.

- Overseas Pharmaceuticals (¥3,006 million, down 32.3% 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, increased accompanying gradual easing of measures implemented to prevent the spread of COVID-19 infection, such as postponement of non-urgent and non-emergency medical procedures. The

Company's sales fell year on year, reflecting the impact of lower shipments in the first quarter.

Local sales volume in the U.S. and the Company's sales of SUPARTZ FX, an intra-articular 5-injection viscosupplement for the treatment of knee osteoarthritis, declined year on year due to continuation of the trend in the U.S. market toward preference for products that require a low number of injections due to a decrease in outpatient services.

Local sales of Seikagaku products in the U.S. market have been picking up since mid-May, when economic activity resumed, and the recovery trend was ongoing as of the end of the second quarter.

Although the impact of curtailment of outpatient services in some areas of China continued, the market is following a recovery trend, and local sales volume of ARTZ was at the prior-year level. The Company's sales decreased, reflecting factors including adjustment of shipments to the sales partner.

- Bulk Products and Contract Development and Manufacturing Organization * (¥948 million, up 77.1% year on year)

Sales increased due to higher shipments of bulk products in Japan and overseas as well as the addition of sales from contract development and manufacturing organization at Dalton Chemical Laboratories, Inc.

*Starting from the second quarter under review, the sales of Dalton Chemical Laboratories, Inc., which became a subsidiary in March 2020, are included in the pharmaceuticals business segment.

As a result of these developments, sales from the pharmaceuticals business segment fell 16.4% year on year to ¥10,234 million.

LAL Business

Sales of overseas subsidiary Associates of Cape Cod, Inc. were at the prior-year level due to growth in sales of Clinical Diagnostic (Fungitell) reagents, despite a decrease in sales of Bacterial Endotoxin Testing (BET) reagents. However, sales from the LAL business segment decreased 0.6% year on year to ¥3,299 million, reflecting the impact of lower sales in Japan.

Since the endotoxin-detecting reagents and contract research services offered in the LAL business are used in quality management of injectable pharmaceuticals and certain medical devices, at this time the Company expects the impact from COVID-19 infection to be limited.

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

Although in the second quarter the Company achieved the full-year forecast for ordinary income in the consolidated financial forecast for fiscal 2020 announced on September 24, 2020, in light of expected concentration of R&D and other expenses in the third quarter and beyond, there is no change to the forecast of consolidated financial results.

Sales performance in Japan and the United States, key markets for Seikagaku's business, bottomed out in the first quarter, and deliveries to medical institutions have for the most part returned to the prior-year level since July. For this reason, the Company has calculated the forecast of consolidated financial results based on the assumption that this situation will continue in the third quarter and beyond and economic activity will not be severely restricted again. If a significant change is expected due to a change in the spread of COVID-19 infection, Seikagaku will promptly announce a revision of the forecast.

Reference: Forecast of Consolidated Business Results for the Fiscal Year Ending March 31, 2021
(April 1, 2020 to March 31, 2021)

(Percentages indicate changes from the previous 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 2020	26,650	(7.0)	550	(71.9)	1,400	(64.8)	1,150	-

Note: The exchange rate since the third quarter assumption is ¥105 to the U.S. dollar.

(3) Research and Development Activities

To contribute to healthy and fulfilling lives for people around the world, the Company 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 drugs, which hold the key to future business growth, the Company 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 2020 were ¥1,615 million, or 23.2% of net sales. The status of progress of principal R&D activities is described below.

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

An additional Phase III clinical study of SI-6603 in the U.S. was initiated in February 2018, and the Company proceeded with the study under a plan to complete follow-up observations in November 2022. However, a delay has occurred in the clinical trial schedule, partly because of discontinuation of the study at some medical institutions and an increase in the number of subjects postponing hospital visits, both due to the spread of COVID-19 infection in the U.S. As of September 30, 2020, against a backdrop of a recovery trend in the status of trial site operation, measures such as effective recruitment activities in subject enrollment and the rapid start-up of new trial sites in cooperation with a local contract research organization (CRO) have been successful, and the study is steadily progressing. The Company will continue to conduct the study while taking measures to reduce the risk of COVID-19 infection.

SI-613 (treatment for osteoarthritis: developed in Japan and the U.S.)

In January 2020, the Company submitted a new drug application for manufacturing and marketing approval in Japan relating to the efficacy and effectiveness of SI-613 in the treatment of osteoarthritis (knee joint, hip joint, ankle joint) based on the results of three Phase III clinical studies conducted in Japan. The Company is appropriately responding to inquiries from the regulatory authorities, there has been no impact on the examination due to COVID-19 as of September 30, 2020, and the Company believes that the examination is proceeding smoothly.

Note: the Company entered into an agreement with Eisai Co., Ltd. concerning a marketing alliance in South Korea for SI-613 in September 2020. This is the second market for which the Company has formed an alliance with Eisai, following conclusion of an agreement concerning a co-development and marketing alliance in China in April 2020.

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

Although Phase I/II clinical studies of SI-722 were initiated in November 2019, a delay has occurred in the clinical trial schedule due to the spread of COVID-19 infection in the U.S. Up to the first quarter, when the virus was spreading, there were adverse impacts from COVID-19, such as discontinuation of the study at medical institutions and an increase in the number of subjects postponing hospital visits. However, due to resumption of economic activity, all test sites were operating as of September 30, 2020. Currently, the Company is proceeding with subject enrollment in cooperation with a local CRO.

SI-449 (adhesion barrier: developed in Japan)

Although a pivotal study to confirm effectiveness prevention of post-operative adhesion formation), safety, and usability was initiated in May 2020, a delay has occurred in the clinical trial schedule due to the spread of COVID-19 infection. Currently, the Company is taking measures to make up for the delay, such as expanding the trial site network and implementing a remote response for facilities where visiting is restricted.

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