

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

Listed exchanges: Tokyo Stock Exchange (First Section)

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 2020
(from April 1, 2020 to June 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 three months of fiscal 2020	6,972	(8.8)	305	(68.3)	610	(51.2)
First three months of fiscal 2019	7,649	5.8	964	81.7	1,251	(19.5)

	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 2020	529	(46.0)	9.39	-
First three months of fiscal 2019	980	(18.6)	17.38	-

(Note) Comprehensive income:

First three months of fiscal 2020: 957 million yen [21.8%]

First three months of fiscal 2019: 786 million yen [50.4%]

(2) Consolidated Financial Position

	Total assets	Total equity	Equity ratio
	Millions of Yen	Millions of Yen	%
As of June 30, 2020	67,238	59,991	89.2
As of March 31, 2020	68,501	59,767	87.2

(Reference) Shareholders' equity:

As of June 30, 2020: 59,991 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	-	-	-	-	-
Fiscal 2020 (Forecast)	-	-	-	-	-

(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)

At this time it would be difficult to reasonably assess the impact of the COVID-19 infection on the Company’s business and financial results on the basis of the situation at the end of the first quarter. Since the COVID-19 infection is spreading in Japan and the U.S., key markets for the Company, Accordingly, the Company has not yet determined a forecast of consolidated financial results for the fiscal year ending March 31, 2021. The Company will carefully examine the impact of the COVID-19 infection on the financial results and promptly make an announcement once it becomes possible to determine a forecast.

*** 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, 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 June 30, 2020	397,767 shares	As of March 31, 2020	397,767 shares
(c) Average number of shares issued during the period (three months)	First three months of fiscal 2020	56,416,326 shares	First three months of fiscal 2019	56,403,902 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, 2021.

1. Results of Operations for the First Quarter of Fiscal 2020 (Three-Month Period Ended June 30, 2020)

(1) Qualitative explanation on quarterly financial results

In the first three months (April 1 to June 30, 2020) of the fiscal year ending March 31, 2021 (fiscal 2020), net sales were ¥6,972 million, down 8.8% 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 the COVID-19 infection and postponement of non-urgent and non-emergency medical procedures in the U.S.

Operating income fell 68.3% year on year to ¥305 million as a result of the sales decrease and an increase in R&D expenses attributable to costs related to measures to promote subject enrollment for an additional clinical study underway in the U.S. for SI-6603, a treatment for lumbar disc herniation. Ordinary income fell 51.2% year on year to ¥610 million, reflecting positive factors including the recording of royalty income and a decrease in foreign exchange loss, and net income attributable to owners of parent fell 46.0% year on year to ¥529 million.

1) Net sales by segment

Pharmaceutical Business

- Domestic Pharmaceuticals (¥3,694 million, up 0.1% year on year)

Amid overall market contraction for ARTZ, a joint function improving agent for knee osteoarthritis, deliveries to medical institutions decreased year on year due to the impact of a decrease in outpatient services accompanying the spread of the COVID-19 infection. Market share increased, reflecting the effectiveness of measures to acquire new user facilities implemented in the previous fiscal year. Although shipments increased year on year, the Company's sales fell due to the impact of NHI drug price reductions.

Although the overall market contraction for the OPEGAN series of ophthalmic viscoelastic devices began to contract due to a decrease in the number of cataract surgeries accompanying the spread of the COVID-19 infection, deliveries to medical institutions increased due to altered shipments of 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 for a competing product and a decrease in the number of endoscopic surgeries accompanying the spread of the COVID-19 infection.

To provide the opportunity for treatment with HERNICORE, a treatment for lumbar disc herniation, to greater numbers of patients, the Company continues to provide information and to collect post-marketing safety data to ensure appropriate use and safety. In the first quarter, deliveries of HERNICORE to medical institutions and the Company's sales 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 the COVID-19 infection.

- Overseas Pharmaceuticals (¥1,138 million, down 41.8% 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, fell year on year due to the impact of factors including the lockdown of urban areas and postponement of non-urgent and non-emergency medical procedures accompanying the spread of the COVID-19 infection.

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 a continuing trend in the U.S. market toward preference for products that require a low number of injections, coupled with the impact of the COVID-19 infection.

Local sales of Seikagaku products in the U.S. market have followed a recovery trend since mid-May, when lockdowns were gradually lifted and economic activity began to resume.

Although economic activity resumed in China (P.R.C.) at a comparatively early date, local sales volume and the Company's sales of ARTZ decreased, reflecting the impact of continued curtailment of outpatient services in some areas even after April.

- Bulk Products (¥295 million, up 1.7% year on year)

The Company's sales were at the prior-year level, despite intensification of competition for hyaluronic acid.

As a result of these developments, sales from the pharmaceuticals business segment fell 13.6% year on year to ¥5,128 million.

LAL Business

Sales of Bacterial Endotoxin Testing (BET) and Clinical Diagnostic (Fungitell) reagents increased thanks to reinforcement of sales activities at overseas subsidiary Associates of Cape Cod, Inc., and sales of the LAL business rose 7.7% year on year to ¥1,844 million. *

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, and at this time the Company expects the impact from the COVID-19 infection to be limited. However, it is unclear when the COVID-19 infection will subside, and the business may be affected if the situation becomes prolonged.

*Since Associates of Cape Cod, Inc.'s fiscal year ends in December, the impact on sales of the spread of the COVID-19 infection was immaterial during the period from January to March 2020, the Company's first quarter.

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

At this time it would be difficult to reasonably assess the impact of the COVID-19 infection on the Company's business and financial results on the basis of the situation at the end of the first quarter. Since the COVID-19 infection is spreading in Japan and the U.S., key markets for the Company, Accordingly, the Company has not yet determined a forecast of consolidated financial results for the fiscal year ending March 31, 2021. The Company will carefully examine the impact of the COVID-19 infection on the financial results and promptly make an announcement once it becomes possible to determine a forecast.

(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, as of June 30, 2020 the Company anticipates a delay of approximately six months, 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 the COVID-19 infection in the U.S. If a lockdown is ordered because of an upward trend in the COVID-19 infection cases in a state where many trial sites are located, an additional delay in subject enrollment would be anticipated. The Company is currently steadily implementing 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), while placing the highest priority on the situation at medical institutions and prevention of infection of patients and medical personnel.

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 and believes that the examination is proceeding according to schedule at this time.

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

A Phase I clinical study of SI-722 was completed in the U.S., and Phase I/II clinical studies were initiated in November 2019. However, as of June 30, 2020 the Company expects a delay of approximately four months in the clinical trial plan due to the spread of the COVID-19 infection in the U.S. If infection in the U.S. spreads further and a lockdown is ordered in a state where trial sites are located, an adverse impact on subject enrollment is anticipated. The Company is currently endeavoring to conduct the trial in cooperation with a local CRO while placing the highest priority on the situation at medical institutions and prevention of infection of patients and medical personnel.

SI-449 (adhesion barrier: developed in Japan)

Since a clinically useful effect was confirmed in a pilot study of SI-449 initiated in May 2018, a pivotal study to confirm adhesion prevention effect, safety, and operability was initiated in May 2020. The Company is proceeding carefully with preparations for the start of subject enrollment, placing the highest priority on preventing infection of patients, medical personnel, and others with the COVID-19 infection.

#####