February 5, 2021

SEIKAGAKU CORPORATION
Consolidated Financial Results (Japan GAAP) (Summary) for the First Nine Months of Fiscal 2020 (Nine-Month Period Ended December 31, 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 Nine Months of Fiscal 2020
(from April 1, 2020 to December 31, 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 nine months of fiscal 2020	20,813	(10.4)	1,459	(55.3)	2,113	(45.4)
First nine months of fiscal 2019	23,240	7.7	3,265	141.6	3,868	31.0

	Net income attributable to owners of parent		Net income per share	Diluted net income per share
	Millions of Yen	%	Yen	Yen
First nine months of fiscal 2020	1,879	-	33.31	-
First nine months of fiscal 2019	(9,781)	-	(173.40)	-

(Note) Comprehensive income:
First nine months of fiscal 2020: 1,857 million yen [- %]
First nine months of fiscal 2019: (9,083) million yen [- %]

(2) Consolidated Financial Position

	Total assets	Total equity	Equity ratio
	Millions of Yen	Millions of Yen	%
As of December 31, 2020	66,664	60,267	90.4
As of March 31, 2020	68,501	59,767	87.2

(Reference) Shareholders' equity:
As of December 31, 2020: 60,267million yen
As of March 31, 2020: 59,767million 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	27,500	(4.0)	850	(56.6)	2,050	(48.5)	1,700	—	30.13

(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 December 31, 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 December 31, 2020	384,421 shares	As of March 31, 2020	397,767 shares
(c) Average number of shares issued during the period (nine months)	First nine months of fiscal 2020	56,424,531 shares	First nine months of fiscal 2019	56,411,600 shares

*** This financial reports are not subject to the quarterly review procedures.**

*** 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 Nine Months of Fiscal 2020
(Nine-Month Period Ended December 31, 2020)

(1) Qualitative explanation on quarterly financial results

In the first nine months (April 1 to December 31, 2020) of the fiscal year ending March 31, 2021 (fiscal 2020), net sales were ¥20,813 million, down 10.4% year on year. The result is attributable to sales decrease in 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. These events contrasted with the positive impact on the sales of the consolidation of Dalton Chemical Laboratories, Inc. as a wholly owned subsidiary in March 2020.

Operating income fell 55.3% year on year to ¥1,459 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, reflecting 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 45.4% year on year to ¥2,113 million, reflecting the decline in operating income, despite positive factors that included the recording of royalty income related to overseas products. Net income attributable to owners of parent was ¥1,879 million, turning positive following a net loss of ¥9,781 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.

Net sales by segment

Pharmaceuticals Business

- Domestic Pharmaceuticals (¥9,617 million, down 16.2% 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 compared to the same period of the previous fiscal year. Nevertheless, switching from competing products to ARTZ continued, and market share increased, reflecting factors that included the continuing effectiveness of measures to acquire new user facilities. After following a recovery trend since June, the market had once again softened as of December due to the renewed spread of COVID-19 infection from November onward. 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 aimd a decrease in the number of cataract surgeries accompanying the spread of COVID-19 infection, deliveries to medical institutions and market share 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 reductions.

The Company’s sales of MucoUp, a submucosal injection agent for endoscopic surgery, fell year on year, reflecting the impact of a low-price sales offensive for competing products 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 first nine months 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 (¥4,700 million, down 22.3% year on year)

Although local sales volume in the U.S. of Gel-One, an intra-articular single-injection viscosupplement for the treatment of knee osteoarthritis, was substantially affected in the first quarter by the spread of COVID-19 infection, volume increased from the second quarter onward accompanying easing of measures implemented to prevent the spread of infection, such as postponement of non-urgent and non-emergency medical procedures.

The Company's sales fell year on year, reflecting the substantial 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 coupled with 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 third quarter.

Although curtailment of outpatient services in some areas of China continues, the impact on the market has been minimal, and local sales volume of ARTZ increased. The Company's sales decreased, reflecting factors including adjustment of shipments to the sales partner in the second quarter.

- Bulk Products and Contract Development and Manufacturing Organization* (¥1,535 million, up 84.6% year on year)

Sales increased due to the addition of sales from contract development and manufacturing at Dalton Chemical Laboratories, Inc., despite lower sales of bulk products.

*Starting from the second quarter, 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 13.6% year on year to ¥15,853 million.

LAL Business

Sales from the LAL business segment increased 1.4% year on year to ¥4,960 million as both sales of overseas subsidiary Associates of Cape Cod, Inc., and sales in Japan increased slightly.

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 impact from COVID-19 infection is limited.

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

The Company has revised its consolidated financial forecast for fiscal 2020 ending March 31 2021, which was announced on September 24, 2020, to incorporate results of operations through the first nine months of the fiscal year as well as various factors that can be foreseen at this time.

Net sales are expected to exceed the previous forecast, reflecting softer-than-expected-impact of COVID-19 on sales of overseas pharmaceuticals and overseas sales in the LAL business.

As for the earnings outlook, operating income is expected to exceed the previous forecast, with a projected increase in net sales compared to the previous forecast compensating for higher R&D expenses.

Ordinary income and net income attributable to owners of parent are also expected to exceed the previous forecasts, reflecting a projected increase in royalty income related to overseas products.

Seikagaku forecasts R&D expenses of ¥7,700 million (¥300 million above the previous forecast of ¥7,400 million).

Note:

1. The exchange rate assumption to be used in the forecast of consolidated financial results for the fourth quarter onward is ¥103 to the U.S. dollar.
2. Although the Company achieved the full-year consolidated forecasts for operating income, ordinary income, and net income attributable owners of parent in the third quarter, the revised forecast reflects expected concentration of R&D and other expenses in the fourth quarter.

(Millions of yen)

	Net sales	Operating income	Ordinary income	Net income attributable to owners of parent	Net income per share (Yen)
Previous forecast (A)	26,650	550	1,400	1,150	20.38
Revised forecast (B)	27,500	850	2,050	1,700	30.13
Change (B-A)	850	300	650	550	―
Change (%)	3.2	54.5	46.4	47.8	―
Reference: Result for fiscal 2019	28,642	1,960	3,981	(10,839)	(192.15)

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.

(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 nine months of fiscal 2020 were ¥5,380 million, or 25.9% 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 December 31, 2020, against a backdrop of a recovery trend in the status of trial site operation, the Company is 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) and endeavoring to promote steady enrollment and minimize delays. 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 application was deliberated at a meeting of the Second Committee on New Drugs of the Pharmaceutical Affairs and Food Sanitation Council (PAFSC) held in January 2021, and the Committee recommended approval of SI-613 for use in the treatment of osteoarthritis in the knee joint and hip joint. The Company will continue to respond appropriately in cooperation with the sales partner in order to obtain the manufacture and sales approval.

SI-722 (treatment of Interstitial cystitis and bladder pain syndrome: developed in the U.S.)

Phase I/II clinical studies of SI-722 were initiated in November 2019, and although a delay occurred in the clinical trial schedule due to the spread of COVID-19 infection in the U.S., subject enrollment was completed in January 2021.

#######