SEIKAGAKU CORPORATION

Consolidated Financial Results (Japan GAAP) (Summary) for the First Nine Months of Fiscal 2021 (Nine-Month Period Ended December 31, 2021)

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 2021

(from April 1, 2021 to December 31, 2021)

(1) Consolidated Financial Results

(Percentages indicate changes from the same period in the previous fiscal year)

(referringes increase enanges 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 2021	28,145	37.0	6,234	283.7	6,905	231.5	
First nine months of fiscal 2020	20,550	(6.9)	1,624	(50.2)	2,083	(46.1)	

	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 2021	5,364	188.6	95.25	-	
First nine months of fiscal 2020	1,858	-	32.94	-	

(Note) Comprehensive income:

First nine months of fiscal 2021: 6,164 million yen [235.6 %] First nine months of fiscal 2020: 1,836 million yen [- %]

(2) Consolidated Financial Position

	Total assets	Total equity	Equity ratio	
	Millions of Yen	Millions of Yen	%	
As of December 31, 2021	76,344	67,933	89.0	
As of March 31, 2021	69,915	63,604	91.0	

(Reference) Shareholders' equity:

As of December 31, 2021: 67,933million yen As of March 31, 2021: 63,604million yen

2. Dividends

	Dividends per share							
	1st Quarter	2nd Quarter	3rd Quarter	Year-end	Annual			
	Yen	Yen	Yen	Yen	Yen			
Fiscal 2020	-	10.00	-	14.00	24.00			
Fiscal 2021	-	15.00	-					
Fiscal 2021				15.00	30.00			
(Forecast)				15.00	30.00			

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

3. Forecast of Consolidated Financial Results for Fiscal 2021 (from April 1, 2021 to March 31, 2022)

(Percentages indicate changes from the previous fiscal year)

	Net	sales	es 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 2021	32,200	16.1	4,550	102.3	4,650	53.7	3,650	(14.4)	64.83

(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: 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)
- (b) Number of treasury stock at the end of the period
- (c) Average number of shares issued during the period (nine months)

As of December 31, 2021	56,814,093 shares	As of March 31, 2021	56,814,093 shares
As of December 31, 2021	567,822 shares	As of March 31, 2021	384,421 shares
First nine months of fiscal 2021	56,317,323 shares	First nine months of fiscal 2020	56,424,531 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 2021 (Nine-Month Period Ended December 31, 2021)

(1) Qualitative explanation on quarterly financial results

In the first nine months (April 1 to December 31, 2021) of the fiscal year ending March 31, 2022 (fiscal 2021), net sales were \(\frac{\text{\$\text{\$Y28,145\$}}}{145}\) million, up 37.0% year on year. The result is attributable to a rebound from the impact of the spread of COVID-19 infection in Japan and abroad in the first nine months of the previous fiscal year as well as a substantial increase in royalty income (reclassified from non-operating income to net sales beginning in fiscal 2021) and solid growth from overseas products, which offset the impact of National Health Insurance (NHI) drug price reductions in Japan.

Operating income rose 283.7% year on year to ¥6,234 million, with the sales increase more than offsetting higher SGA expenses—mainly R&D expenses accompanying progress with an additional clinical study underway in the U.S. for SI-6603, a treatment for lumbar disc herniation. Ordinary income rose 231.5% year on year to ¥6,905 million, and net income attributable to owners of parent rose 188.6% to ¥5,364 million.

Net sales by segment

Pharmaceuticals Business

- Domestic Pharmaceuticals (¥9,173 million, down 0.2% year on year)

Deliveries to medical institutions of ARTZ, a joint function improving agent for knee osteoarthritis, increased year on year as a result of successful measures to promote switching from competing products coupled with a market rebound following contraction in the first nine months of the previous fiscal year caused by the spread of COVID-19 infection. The Company's sales were at the prior-year level, with volume growth offsetting the impact of NHI drug price reductions.

With regard to the joint function improving agent JOYCLU, launched on May 19, 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 to increase awareness of these side effects among healthcare professionals. The Company will continue cooperative efforts with sales partner Ono Pharmaceutical Co., Ltd. to proactively gather side effects reports and other information and provide safety-related information and will strive for early identification of the cause of the side effects with the cooperation of medical professionals and institutions.

Deliveries to medical institutions of the OPEGAN series of ophthalmic viscoelastic devices increased year on year, reflecting a rebound following market contraction in the first nine months of the previous fiscal year amid a decrease in the number of cataract surgeries accompanying the spread of COVID-19 infection. The Company's sales fell as a result of NHI drug price reductions and a decline in shipments from a high level in the first nine months of fiscal 2020.

The Company's sales of MucoUp, a submucosal injection agent for endoscopic surgery, rose as a result of bringing forward shipments to the sales partner.

Deliveries to medical institutions and the Company's sales of HERNICORE, a treatment for lumbar disc herniation, increased thanks to steady progress with market penetration attributable to active information provision activities directed at medical institutions carried out together with the sales partner.

- Overseas Pharmaceuticals (¥6,743 million, up 44.6% 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, increased year on year, reflecting successful measures by the sales partner to promote switching from competing products coupled with continuation of the trend toward preference for single-injection products.

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 rebound from the powerful impact on the spread of COVID-

19 infection experienced in the first three months of the previous fiscal year, despite continuation of unfavorable market conditions for multiple-injection products. The Company's sales increased as a result of bringing forward shipments to avoid distribution risk.

In an increasingly difficult market environment due to factors including the Chinese government's pricecurbing policy, local sales volume in China of ARTZ increased because of active sales promotion and the positive effects of marketing structure enhancement. The Company's sales rose sharply, reflecting concentration of shipments in the first nine months in addition to the local sales volume increase.

- Bulk Products and Contract Development and Manufacturing Organization *¹ (¥1,952 million, up 27.2% year on year)

Although sales of bulk products declined, overall sales increased because of growth in sales of contract development and manufacturing services at overseas subsidiary Dalton Chemical Laboratories, Inc. and other services.

As a result of these developments and a substantial increase in royalty income*2 (\xi 3,550 million, up 1,714.0% year on year), sales from the Pharmaceuticals business segment rose 37.4% year on year to \xi 21,420 million.

*1 Starting from the consolidated financial results for the second quarter of fiscal 2020, the sales of Dalton Chemical Laboratories, Inc., which became a subsidiary in March 2020, are included in the Pharmaceuticals business.

*2 Beginning in fiscal 2021, royalty income has been reclassified from non-operating income to net sales.

LAL Business

Sales from the LAL business segment increased 35.6% year on year to ¥6,725 million due to an increase in sales of Bacterial Endotoxin Testing (BET) reagents, Clinical Diagnostic (Fungitell) reagents and to higher orders for BET contract services thanks to reinforcement of sales activities at overseas subsidiary Associates of Cape Cod, Inc. and steady sales in Japan.

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

Although in the third quarter the Company achieved the full-year income forecasts in the forecast of consolidated financial results announced on May 13, 2021, the result is attributable to concentration in the first nine months of sales drivers such as royalty income and bringing forward of shipments of overseas pharmaceuticals. In light of anticipated higher R&D expenses in the fourth quarter to result from costs related to measures to promote subject enrollment for an additional clinical study for SI-6603 and the impact on the sale of JOYCLU of issuance of the Blue Letter, there is no change in the forecast of full-year consolidated financial results.

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 2021 were ¥5,855 million, or 20.8% of net sales

(23.8% excluding royalties).

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

SI-449 (adhesion barrier: developed in Japan)

A pilot study in the field of gynecology was initiated in November 2021 for the purpose of expanding the scope of application of SI-449 by confirming usability and safety in gynecology.

Although a pivotal study of SI-449 in the field of gastroenterological surgery was initiated in May 2020, a delay has occurred in the clinical trial schedule due to the spread of COVID-19 infection. The Company is continuing to take 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.

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 or mitigate post-operative adhesion formation 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 on the other R&D activities.

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