## SEIKAGAKU CORPORATION **Consolidated Financial Results (Japan GAAP) (Summary)** for the First Nine Months of Fiscal 2022 (Nine-Month Period Ended December 31, 2022)

Listed exchanges: Tokyo Stock Exchange (Prime Market) 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 2022 (from April 1, 2022 to December 31, 2022)

## (1) Consolidated Financial Results

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

	Net sales Operation		Operatin	g income	Ordinary income	
	Millions of Yen	%	Millions of Yen	%	Millions of Yen	%
First nine months of fiscal 2022	26,162	(7.0)	3,407	(45.4)	4,218	(38.9)
First nine months of fiscal 2021	28,145	37.0	6,234	283.7	6,905	231.5

	Net income a owners o		Net income per share	Diluted net income per share	
	Millions of Yen	%	Yen	Yen	
First nine months of fiscal 2022	3,628	(32.4)	65.42	-	
First nine months of fiscal 2021	5,364	188.6	95.25	-	

(Note) Comprehensive income:

First nine months of fiscal 2022: 6,471 million yen [5.0%] First nine months of fiscal 2021: 6,164 million yen [235.6%]

## (2) Consolidated Financial Position

	Total assets	Total equity	Equity ratio	
	Millions of Yen	Millions of Yen	%	
As of December 31, 2022	76,636	69,767	91.0	
As of March 31, 2022	75,244	66,340	88.2	

(Reference) Shareholders' equity:

As of December 31, 2022: 69,767 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: No

	Net	sales	Operatin	g income	Ordinary	y 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

#### **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)

(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)	As of December 31, 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 December 31, 2022	2,273,029 shares	As of March 31, 2022	567,822 shares
(c) Average number of shares issued during the period (six months)	First nine months of fiscal 2022	55,468,720 shares	First nine months of fiscal 2021	56,317,323 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 Nine Months of Fiscal 2022

## (Nine-Month Period Ended December 31, 2022)

## (1) Qualitative explanation on quarterly financial results

In the first nine months (April 1 to December 31, 2022) of the fiscal year ending March 31, 2023 (fiscal 2022), net sales were  $\frac{1}{2}26,162$  million, down 7.0% 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 45.4% year on year to \$3,407 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 38.9% to \$4,218 million and 32.4% to \$3,628 million, respectively, declining less steeply than operating income because of the recording of foreign exchange gains due to yen depreciation.

#### 1) Net sales by segment

#### **Pharmaceuticals Business**

#### - Domestic Pharmaceuticals (¥8,850 million, down 3.5% year on year)

Deliveries to medical institutions of ARTZ, a joint function improvement agent for knee osteoarthritis, increased year on year 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 shipment timing.

The Company's sales of the joint function improvement agent JOYCLU, launched on May 19, 2021, increased year on year, reflecting a longer selling period than in the first nine 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 market gradually returning to the pre-COVID growth trend. The Company's sales rose as a result of an increase in shipment volume, despite the impact of NHI drug price reductions.

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 nine months 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 shipment timing.

### - Overseas Pharmaceuticals (¥6,922 million, up 2.7% 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, rose slightly, despite continuation of unfavorable market conditions due to the trend toward preference for products that require fewer injections. The Company's sales were at the prior-year

level as a result of shipment timing.

Local sales volume in China of ARTZ fell sharply, reflecting the impact of factors including limitation of access to outpatient services 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.

## - Bulk Products and Contract Development and Manufacturing Organization (¥2,178 million,

## up 11.5% 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 16.2% year on year to ¥17,953 million.

#### LAL Business

Sales from the LAL business segment increased 22.1% year on year to ¥8,209 million, reflecting the impact of yen depreciation on the results from 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 income in the first nine months of fiscal 2022 has already reached the full-year forecast results in the consolidated financial forecast for fiscal 2022, which was announced on November 8, 2022, in light of expected fourth-quarter developments such as a decrease in sales of contract testing services at an overseas subsidiary, higher expenses to result from concentration of R&D expenses in the quarter and soaring fuel costs, and concentration of periodic plant maintenance because of a semiconductor shortage and other factors, there is no change to the forecast of 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 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 nine months of fiscal 2022 were ¥5,355 million, or 20.5% of net sales (excluding royalties).

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

### SI-614 (treatment for dry eye: developed in the U.S.)

Subject enrollment has been completed for a Phase III clinical study being conducted since May 2022 with the objective of evaluating efficacy and safety. After obtaining data from the clinical study currently underway, the Company plans to select a sales partner and conduct a second Phase III clinical study and a long-term study.

SI-614 is a substance produced by introducing a hydrophobic group into hyaluronic acid using Seikagaku's own proprietary technology. Ocular instillation of SI-614 in patients is expected to improve symptoms of dry eye by stabilizing the tear film and promoting corneal epithelial wound healing. Through development of SI-614, the

Company aims to provide a new option for the treatment of dry eye.

There is no substantial change in the other R&D activities.

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