

**SEIKAGAKU CORPORATION**  
**Consolidated Financial Results (Japan GAAP) (Summary)**  
**for the First Three Months of Fiscal 2022**  
**(Three-Month Period Ended June 30, 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 Three Months of Fiscal 2022**  
**(from April 1, 2022 to June 30, 2022)**

**(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 2022	8,307	(29.5)	1,126	(74.7)	1,714	(62.8)
First three months of fiscal 2021	11,784	71.6	4,446	-	4,613	655.8

	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 2022	1,493	(59.1)	26.62	-
First three months of fiscal 2021	3,652	589.3	64.73	-

(Note) Comprehensive income:

First three months of fiscal 2022: 2,162 million yen [(54.7)%]

First three months of fiscal 2021: 4,772 million yen [398.2%]

**(2) Consolidated Financial Position**

	Total assets	Total equity	Equity ratio
	Millions of Yen	Millions of Yen	%
As of June 30, 2022	74,979	67,303	89.8
As of March 31, 2022	75,244	66,340	88.2

(Reference) Shareholders' equity:

As of June 30, 2022: 67,303 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	-				
Fiscal 2022 (Forecast)		11.00	-	11.00	22.00

(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 June 30, 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 June 30, 2022	1,015,222 shares	As of March 31, 2022	567,822 shares
(c) Average number of shares issued during the period (three months)	First three months of fiscal 2022	56,105,055 shares	First three months of fiscal 2021	56,429,665 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, 2023.

## **1. Results of Operations for the First Quarter of Fiscal 2022 (Three-Month Period Ended June 30, 2022)**

### **(1) Qualitative explanation on quarterly financial results**

In the first three months (April 1 to June 30, 2022) of the fiscal year ending March 31, 2023 (fiscal 2022), net sales were ¥8,307 million, down 29.5% year on year. While the expansion of the LAL business and the effect of the yen depreciation on overseas products, the result is attributable to a substantial decrease in royalty income, a year-on-year decline in shipments of JOYCLU, which in fiscal 2021 were concentrated in the first quarter due to the product launch, and the impact of National Health Insurance (NHI) drug price reductions in Japan.

Operating income fell 74.7% year on year to ¥1,126 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 62.8% to ¥1,714 million and 59.1% to ¥1,493 million, respectively, declining less steeply than operating income because of factors including the recording of foreign exchange gains due to yen depreciation.

### **1) Net sales by segment**

#### **Pharmaceutical Business**

##### **- Domestic Pharmaceuticals (¥2,965 million, down 22.9% year on year)**

Deliveries to medical institutions of ARTZ, a joint function improvement agent for knee osteoarthritis, increased year on year amid signs that the market is recovering from the impact of COVID-19, 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 a shipment schedule adjustment.

The Company's sales of the joint function improvement agent JOYCLU, launched on May 19, 2021, declined substantially year on year, reflecting concentration of shipments in the first quarter of fiscal 2021 in connection with the launch. 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, in April 2022, the Company initiated 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 impact of COVID-19 running its course and the market gradually returning to the pre-COVID growth trend. The Company's sales fell as a result of NHI drug price reductions coupled with an inventory adjustment by the sales partner.

The Company's sales of MucoUp, a submucosal injection agent for endoscopic surgery, increased, reflecting a rebound in shipments from a low level in the first quarter of the previous fiscal year.

Although deliveries to medical institutions of HERNICORE, a treatment for lumbar disc herniation, remained at the prior-year level, the Company's sales rose due to a shipment schedule adjustment.

##### **- Overseas Pharmaceuticals (¥1,788 million, up 12.5% 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 market trend looking ahead to a July 2022 health insurance system change relating to price disclosure and non-recurrence of a volume increase in the first quarter of fiscal 2021 accompanying recovery from the impact of COVID-19. The Company's sales increased substantially, fueled by the impact of yen depreciation and a volume increase resulting from shipment timing.

Local sales volume in the U.S. of SUPARTZ FX, an intra-articular 5-injection viscosupplement for the treatment of knee osteoarthritis, was at the prior-year level, reflecting continuation of unfavorable market

conditions for multiple-injection products due to the trend toward preference for products that require fewer injections. However, the Company's sales rose thanks to the impact of yen depreciation.

Local sales volume in China of ARTZ fell sharply because of a decline in the patient consultation rate due to lockdowns in major cities accompanying the renewed spread of COVID-19. There were no shipments in the first quarter, in accordance with the annual shipping plan, because the sales partner built up inventory in the previous fiscal year due to a packaging material change. Shipments are scheduled to restart in August 2022.

**- Bulk Products and Contract Development and Manufacturing Organization (¥732 million, up 1.7% year on year)**

Overall sales were at the prior-year level. Although sales of contract development and manufacturing and other services of overseas subsidiary Dalton Chemical Laboratories, Inc. fell, sales of bulk products rose.

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 43.5% year on year to ¥5,488 million.

**LAL Business**

Sales from the LAL business segment increased 35.7% year on year to ¥2,819 million, reflecting steady sales in Japan and the contribution from higher sales of Bacterial Endotoxin Testing (BET) reagents and Clinical Diagnostic (Fungitell) reagents and higher orders for contract testing services attributable to reinforcement of sales activities at overseas subsidiary Associates of Cape Cod, Inc.

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

It is difficult at present to prepare reasonable forecasts of consolidated financial results for fiscal 2022, ending March 31, 2023, because it is necessary to assess the progress of efforts underway to identify the cause of shock or anaphylaxis occurring in patients following administration of the joint function improvement agent JOYCLU. Accordingly, the Company will continue to refrain from announcing earnings forecasts at this time. Once it becomes possible to prepare reasonable forecasts, the Company will promptly announce them.

**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 three months of fiscal 2022 were ¥1,687 million, or 20.3% of net sales (excluding royalties).

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

**SI-449 (adhesion barrier: developed in Japan)**

Subject enrollment in a pilot study in the field of gynecology was completed in May 2022. The study is being conducted for the purpose of expanding the scope of application of SI-449 by confirming usability and safety in gynecology.

Although a delay has occurred in the clinical trial schedule of a pivotal study of SI-449 in the field of gastroenterological surgery, conducted since May 2020, due to the spread of COVID-19 infection, subject enrollment is steadily proceeding thanks to the effectiveness of measures such as expanding the trial site network and implementation of 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 post-operative adhesion formation in surgery 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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