

November 8, 2019

SEIKAGAKU CORPORATION
Consolidated Financial Results (Japan GAAP) (Summary)
for the First Six Months of Fiscal 2019
(Six-Month Period Ended September 30, 2019)

Listed exchanges: Tokyo Stock Exchange (First Section)

Stock code number: 4548

URL: <https://www.seikagaku.co.jp/en/>

Scheduled date to commence dividend payment: December 3, 2019

(All amounts have been rounded down to the nearest million yen)

1. Consolidated Financial Results for the First Six Months of Fiscal 2019

(from April 1, 2019 to September 30, 2019)

(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 six months of fiscal 2019	15,555	9.1	2,150	123.1	2,471	(0.2)
First six months of fiscal 2018	14,256	(8.0)	963	(56.6)	2,475	(48.4)

	Net income attributable to owners of parent		Net income per share	Diluted net income per share
	Millions of Yen	%	Yen	Yen
First six months of fiscal 2019	(10,766)	-	(190.86)	-
First six months of fiscal 2018	1,912	(46.1)	33.85	-

(Note) Comprehensive income:

First six months of fiscal 2019: (10,958) million yen [- %]

First six months of fiscal 2018: 1,682 million yen [(58.6) %]

(2) Consolidated Financial Position

	Total assets	Total equity	Equity ratio
	Millions of Yen	Millions of Yen	%
As of September 30, 2019	68,151	61,359	90.0
As of March 31, 2019	80,238	73,036	91.0

(Reference) Shareholders' equity:

As of September 30, 2019: 61,359 million yen

As of March 31, 2019: 73,036 million yen

2. Dividends

	Dividends per share				
	1st Quarter	2nd Quarter	3rd Quarter	Year-end	Annual
	Yen	Yen	Yen	Yen	Yen
Fiscal 2018	-	13.00	-	13.00	26.00
Fiscal 2019	-	13.00	-	-	-
Fiscal 2019 (Forecast)	-	-	-	13.00	26.00

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

3. Forecast of Consolidated Financial Results for Fiscal 2019 (from April 1, 2019 to March 31, 2020)

(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 2019	28,600	0.8	1,350	38.1	3,750	31.2	(11,000)	-	(194.99)

(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 September 30, 2019	56,814,093 shares	As of March 31, 2019	56,814,093 shares
(b) Number of treasury stock at the end of the period	As of September 30, 2019	397,616 shares	As of March 31, 2019	410,176 shares
(c) Average number of shares issued during the period (six months)	First six months of fiscal 2019	56,409,157 shares	First six months of fiscal 2018	56,499,080 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 Six Months of Fiscal 2019

(Six-Month Period Ended September 30, 2019)

(1) Qualitative explanation on quarterly financial results

In the first six months (April 1 to September 30, 2019) of the fiscal year ending March 31, 2020 (fiscal 2019), net sales rose 9.1% year on year to ¥15,555 million. The result is due to growth in the pharmaceuticals business owing to solid performance in pharmaceutical products in Japan and overseas.

Operating income rose 123.1% year on year to ¥2,150 million as a result of increased sales combined with lower R&D expenses. Ordinary income remained approximately unchanged (down 0.2% year on year) to ¥2,471 million, reflecting that gains on sale of investment securities declined and that no royalty income was included for the period. The Company also realized an extraordinary loss of ¥12,304 million as a result of an impairment loss as described in the announcement of extraordinary loss (impairment loss) separately released on November 8, 2019. The impairment charge results from a detailed examination of business conditions and medium- to long-term earnings trends in the pharmaceuticals business. Net income attributable to owners of parent was a net loss of ¥10,766 million compared to a net profit of ¥1,912 million during the same period in the previous fiscal year.

Net sales by segment

Pharmaceuticals Business

- Domestic Pharmaceuticals (¥7,260 million, up 4.1% year on year)

While the overall market for ARTZ, a joint function improving agent for knee osteoarthritis, was generally flat, deliveries to medical institutions were up slightly. The Company's sales rose due to a focus on shipments through the second quarter.

For the OPEGAN series of ophthalmic viscoelastic devices, deliveries to medical institutions and market share grew, and the Company's sales increased, as a result of maintaining favorable performance across the entire OPEGAN series, including steady performance of SHELLGAN.

MucoUp, a submucosal injection agent for endoscopic surgery, had a decrease in the Company's sales due to the impact of the introduction of competing products on the market.

For HERNICORE, a treatment for lumbar disc herniation, deliveries to medical institutions showed a steady increase as the Company's sales rose. The Company continues to engage in information provision activities directed at medical institutions to ensure appropriate use and safety together with the sales partner, leading to steady progress in market penetration.

- Overseas Pharmaceuticals (¥4,439 million, up 29.5% year on year)

In the U.S., Gel-One, an intra-articular single-injection viscosupplement for the treatment of knee osteoarthritis, had sizable increases in local sales volume and the Company's sales, as a result of qualification for preferential reimbursement status with multiple insurance companies and a successful campaign to switch from rival products.

For SUPARTZ FX, an intra-articular 5-injection for the treatment of knee osteoarthritis, the continuation of the trend in the U.S. towards products requiring fewer injections, such as single-injection and 3-injection products, led to a decline in local sales volume, but the Company's sales increased due to the increasing of shipments by advancing them forward.

Regarding ARTZ for China (P.R.C.), local sales volume grew as the sales expansion strategy enjoyed continued success, but the Company's sales fell due to foreign exchange effects.

- Bulk Products (¥535 million, down 0.0% year on year)

While sales of hyaluronic acid increased, sales of chondroitin sulfate declined, leading to flat growth year on year.

As a result of these developments, sales for the pharmaceuticals business segment rose 11.9% year on year to ¥12,236 million.

LAL Business

Although sales declined in Japan, overseas subsidiary Associates of Cape Cod, Inc. has focused on expanding

sales operations for its Bacterial Endotoxin Testing (BET) and Clinical Diagnostic (FungitellR) reagents. Due to strong performance from these product lines, sales of the LAL business rose 0.1% year on year to ¥3,319 million..

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

The Company has revised its consolidated financial forecast for fiscal 2019 ending March 2020, which was announced on May 10, 2019, to incorporate results of operations through the first six months of the fiscal year as well as various factors that can be foreseen at this time.

With regard to net sales, the Company forecasts an increase in sales of Gel-One in the U.S., an intra-articular single-injection viscosupplement for the treatment of knee osteoarthritis, and expects net sales to exceed the previous forecast. With regard to operating income, although R&D expenses is increasing, because of higher sales in addition to a decline in depreciation in conjunction with the impairment loss, the Company expects operating income to exceed the previous forecast. The Company has raised its estimates for ordinary income as a result of increases in royalty income, etc. However, the Company has substantially lowered its forecast of net income attributable to owners of parent. This is because it has included in its financial results an extraordinary loss owing to an impairment loss. The Company forecasts ¥7.0 billion in research and development expenses for the current fiscal year (an increase of 2.9% year on year) with a ratio to sales of 24.5%. The foreign exchange rate assumption for the second half of the fiscal year used in the forecast of consolidated financial results has been unchanged to ¥105 to the U.S. dollar..

(Millions of Yen)

	Net sales	Operating income	Ordinary income	Net income attributable to owners of parent	Net income per share
Previous Forecast (A)	28,250	400	2,300	2,000	35.46
Revised Forecast (B)	28,600	1,350	3,750	(11,000)	(194.99)
Difference (B - A)	350	950	1,450	(13,000)	-
Difference (%)	1.2	237.5	63.0	-	-
(Reference) Prior-year Results (fiscal 2018)	28,384	977	2,859	2,244	39.76

Notes: 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.

2) Research and Development Activities

Research and Development Activities

To contribute to healthy and fulfilling lives for people around the world, the Company focuses 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 engages in efficient R&D activities by focusing on target compounds and prioritizing target diseases.

Total R&D expense in the financial results for the first six months of the fiscal year came to ¥3,007 million, or 19.3% of net sales.

The progress status of principal R&D activities is as follows.

SI-6603 (treatment of lumbar disc herniation: developed in the U.S.)

The Company initiated an additional Phase III clinical study in the U.S. in February 2018 and is currently enrolling subjects. In order to raise the probability of success, this study enforces a strict standard for enrolling subjects. Also, time is needed for starting the treatment facilities. For these reasons, progress has slowed more than expected. As a result, the Company has reviewed the original study plan and extended the completion date

by two years (follow-up observations scheduled for completion in November 2022).

SI-613 (treatment for osteoarthritis and enthesopathy: developed in Japan and the U.S.)

SI-613 has completed three studies for a Phase III clinical study in Japan. In light of the results, Seikagaku intends to apply for drug approval during the current fiscal year and is proceeding with preparations.

SI-722 (treatment for interstitial cystitis and bladder pain syndrome [IC/BPS]: developed in the U.S.)

SI-722 has completed a Phase I clinical study in the U.S. In November 2019, it is starting a Phase II/II clinical study. This clinical study will evaluate the drug for safety, tolerability, and pharmacokinetics, and will conduct an exploratory evaluation of its effectiveness. SI-722 is a novel chemical compound in which a steroid is conjugated with chondroitin sulfate using Seikagaku's proprietary glycosaminoglycan (GAG) modification technology and drug delivery systems (DDS). We believe that intravesically instilled SI-722 provides sustained release of the steroid having anti-inflammatory activity resulting in a demonstration of long-lasting improvement in the conditions of frequent urination and bladder pain. SI-722 is targeted at enhancing patients' quality of life by providing new options for the treatment of interstitial cystitis and bladder pain syndrome.

There are no major changes to Seikagaku's other R&D activities.

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