May 10, 2019

SEIKAGAKU CORPORATION
Consolidated Financial Results (Japan GAAP) (Summary) for the Fiscal 2018 (Year Ended March 31, 2019)

Listed exchanges: Tokyo Stock Exchange (First Section)
Stock code number: 4548
URL: https://www.seikagaku.co.jp/en/
Date of ordinary general meeting of shareholders (Planned): June 19, 2019
Date of dividend payment (Planned): June 20, 2019

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

1. Consolidated Financial Results for the Fiscal 2018(from April 1, 2018 to March 31, 2019)

(1) Consolidated Financial Results

(Percentages indicate changes from the prior fiscal year)

	Net sales		Operating income		Ordinary income		Net income attributable to owners of parent	
	Millions of Yen	%	Millions of Yen	%	Millions of Yen	%	Millions of Yen	%
Fiscal 2018	28,384	(5.9)	977	(31.3)	2,859	(46.3)	2,244	(42.8)
Fiscal 2017	30,175	2.0	1,421	10.9	5,327	115.1	3,922	119.4

(Note) Comprehensive income:
Fiscal 2018: 862 million yen[(82.9%)]
Fiscal 2017: 5,054 million yen[91.6%]

	Net income per share	Diluted net income per share	Return on equity	Ordinary income as a percentage of total assets	Operating income as a percentage of net sales
	Yen	Yen	%	%	%
Fiscal 2018	39.76	-	3.1	3.5	3.4
Fiscal 2017	69.30	-	5.4	6.5	4.7

(2) Consolidated Financial Position

	Total assets	Total equity	Equity ratio	Total equity per share
	Millions of Yen	Millions of Yen	%	Yen
Fiscal 2018	80,238	73,036	91.0	1,294.88
Fiscal 2017	84,098	73,945	87.9	1,306.37

(Reference) Shareholders' Equity:
Fiscal 2018: 73,036 million yen
Fiscal 2017: 73,945 million yen

(3) Consolidated Cash Flows

	Net cash flows from operating activities	Net cash flows from investing activities	Net cash flows from financing activities	Cash and cash equivalents at the end of fiscal year
	Millions of Yen	Millions of Yen	Millions of Yen	Millions of Yen
Fiscal 2018	3,121	(1,481)	(1,812)	7,313
Fiscal 2017	5,346	(4,066)	(2,221)	7,511

2. Dividends

	Dividends per share				
	1st Quarter	2nd Quarter	3rd Quarter	Fiscal Year-end	Annual
	Yen	Yen	Yen	Yen	Yen
Fiscal 2017	-	13.00	-	13.00	26.00
Fiscal 2018	-	13.00	-	13.00	26.00
Fiscal 2019 (Forecast)	-	13.00	-	13.00	26.00

	Total dividend payments (Annual)	Dividend payout ratio (Consolidated)	Dividends as a percentage of total equity (Consolidated)
	Millions of Yen	%	%
Fiscal 2017	1,471	37.5	2.0
Fiscal 2018	1,466	65.4	2.0
Fiscal 2019 (Forecast)		73.3	

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

(Percentages indicate changes from the prior 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	28,250	(0.5)	400	(59.1)	2,300	(19.6)	2,000	(10.9)	35.46

* Notes

(1) Changes in the status of material subsidiaries during the period: No

(2) Changes in accounting principles, changes in accounting estimates, and retrospective restatements

(a) Changes in accounting principles 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

(3) Number of shares issued (common stock):

(a) Number of shares at the end of the period (including treasury stock)	As of March 31, 2019	56,814,093 shares	As of March 31, 2018	56,814,093 shares
(b) Number of treasury stock at the end of the period	As of March 31, 2019	410,176 shares	As of March 31, 2018	209,947 shares
(c) Average number of shares issued during the period	Fiscal 2018	56,451,671 shares	Fiscal 2017	56,604,365 shares

(Reference) Non-Consolidated Financial Results

Non-Consolidated Financial Results for Fiscal 2018 (from April 1, 2018 to March 31, 2019)

(1) Non-Consolidated Financial Results

(Percentages indicate changes from the prior fiscal year)

	Net sales		Operating income		Ordinary income		Net income	
	Millions of Yen	%	Millions of Yen	%	Millions of Yen	%	Millions of Yen	%
Fiscal 2018	23,144	(8.8)	(168)	-	1,694	(59.5)	1,386	(57.0)
Fiscal 2017	25,371	(0.4)	299	1.7	4,188	181.7	3,225	176.7

	Net income per share	Diluted net income per share
	Yen	Yen
Fiscal 2018	24.57	-
Fiscal 2017	56.99	-

(2) Non-Consolidated Financial Position

	Total assets	Total Equity	Equity ratio	Total Equity per share
	Millions of Yen	Millions of Yen	%	Yen
Fiscal 2018	75,224	68,596	91.2	1,216.16
Fiscal 2017	79,963	70,232	87.8	1,240.77

(Reference) Shareholders' Equity:

Fiscal 2018: 68,596 million yen

Fiscal 2017: 70,232 million yen

***This financial reports are not subject to audit 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. Analysis of Results of Operations

Results of operations for the current fiscal year

In the fiscal year ended March 31, 2019 (fiscal 2018), net sales were ¥28,384 million, down 5.9% year on year. The result is attributable to a sharp decline in sales from the pharmaceuticals business segment due to the impact of National Health Insurance (NHI) drug price reductions in Japan implemented in April 2018, despite growth from the LAL business in Japan and overseas.

With regard to earnings, although selling, general and administrative expenses, mainly R&D expenses, decreased, operating income fell 31.3% year on year to ¥977 million. Ordinary income fell 46.3% year on year to ¥2,859 million, reflecting a sharp decline in royalty income and other factors, despite an increase in gain on sale of investment securities, and net income attributable to owners of parent fell 42.8% year on year to ¥2,244 million.

1) Net sales by segment

Pharmaceutical Business

- Domestic Pharmaceuticals (¥14,161 million, down 12.2% year on year)

Amid overall market contraction, deliveries to medical institutions and market share of ARTZ, a joint function improving agent, increased thanks to sales expansion measures by the sales partner accompanying the introduction of a modified product that meets user needs. The Company's sales fell sharply, reflecting the impact of NHI drug price reductions implemented in April 2018.

Deliveries to medical institutions and market share of the OPEGAN series of ophthalmic viscoelastic devices increased due to strong performance from SHELLGAN. The Company's sales increased slightly, as the higher deliveries to medical institutions and market share compensated for the impact of NHI price decreases.

The Company is striving for a phased rollout of HERNICORE, a treatment for lumbar disc herniation launched in August 2018, by providing information to medical institutions aimed at ensuring appropriate use and safety. Since fiscal 2018 was the launch year, the Company's sales were small.

The Company's sales of MucoUp, a submucosal injection agent for endoscopic surgery, increased slightly.

- Overseas Pharmaceuticals (¥6,511 million, down 8.5% year on year)

In the U.S., the market for hyaluronic acid injectable treatments began to contract on a value basis due to the impact of factors such as intensifying competition and suspension of reimbursement by some insurance companies. In these circumstances, local sales and the Company's sales of Gel-One, an intra-articular single-injection viscosupplement for the treatment of knee osteoarthritis, increased thanks to sales expansion measures by the sales partner. Local sales and the Company's sales of SUPARTZ FX, an intra-articular 5-injection for the treatment of knee osteoarthritis, declined sharply, reflecting the strong impact of suspension of reimbursement requirements.

Local sales of ARTZ in China (P.R.C.) and the Company's sales increased, reflecting successful sales partner sales expansion activities targeting both urban and surrounding areas.

- Bulk Products (¥1,220 million, up 21.4% year on year)

Sales of hyaluronic acid and chondroitin sulfate for pharmaceutical companies increased.

As a result of these developments, sales from the pharmaceuticals business segment fell 9.7% year on year to ¥21,893 million.

LAL Business

Sales of the LAL business rose 9.4% year on year to ¥6,491 million as a result of strong domestic and overseas sales. Overseas subsidiary Associates of Cape Cod, Inc. is focusing on expanding both direct and distributor based sales operations, and its sales of bacterial endotoxin testing (BET) reagents and glucan detecting in vitro clinical diagnostic reagents are increasing.

2) 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 products, 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 and is working to expand and enhance the glycoscience research network in Japan and overseas.

Total R&D expenses in fiscal 2018 were ¥7,148 million, or 25.2% of net sales, and the number of R&D personnel was 233, or 31.3% of the total number of employees, at the end of March 2019.

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

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

SI-6603 (product name in Japan: HERNICORE) is a treatment for lumbar disc herniation being developed in the U.S. Although the expected pharmacological effect was demonstrated in a Phase III clinical study, the study did not meet its primary endpoint of pain improvement. In response to this result, the Company initiated an additional Phase III clinical study in the U.S. in February 2018 and is currently enrolling subjects. The Company plans to increase the probability of success by reflecting in the additional study the knowledge it gained from the results of the previous study.

SI-6603, which contains condoliase as its active pharmaceutical ingredient, is a treatment directly injected into the lumbar disc. It does not require a general anesthesia and is less invasive to the patient than surgical treatment. Since a single injection treatment is expected to improve the symptoms of lumbar disc herniation, SI-6603 is expected to improve the quality of life of patients as a new treatment option.

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

In Japan, the Company is conducting three studies as part of a Phase III clinical study targeting osteoarthritis: a confirmatory study on the knee joint, a clinical study for other joints (hip, ankle, elbow, and shoulder), and a long-term administration study with the primary objective of safety evaluation. In February 2019, in the confirmatory study on the knee joint, the Company obtained topline results indicating that SI-613 demonstrated a statistically significant improvement in WOMAC (a knee pain evaluation index) scores, a primary endpoint of the study, compared with a placebo at twelve weeks after the initial injection. The Company will focus on the progress of the remaining two clinical studies and, after completion of all three studies, will aim to file an application for manufacturing and marketing approval for SI-613 in the first half of 2020, after consideration of the data obtained after completion of all three studies. Also, follow-up observation has been completed in a late-stage Phase II clinical trial in Japan for enthesopathy and a Phase II clinical trial in the U.S. for knee osteoarthritis, and the Company is currently analyzing the data obtained from the studies.

SI-613 is a formulation in which hyaluronic acid and diclofenac (an anti-inflammatory drug) are chemically bound using Seikagaku's own proprietary technology. Since SI-613 combines the pain relief and anti-inflammatory effect of diclofenac designed for sustained release with the joint function improving effect of hyaluronic acid, it is expected to provide prompt and sustained relief of the pain and inflammation associated with osteoarthritis and enthesopathy.

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

Phase II/III clinical trials were completed in January 2015, and the Company is currently considering a Phase III clinical trial based on the data obtained and proceeding with selection of a sales partner.

SI-614 is a modified hyaluronate that is produced using proprietary technology. Ocular instillation of SI-614 in patients with dry eye is expected to protect the ocular surface and promote corneal wound healing.

SI-449 (adhesion barrier: developed in Japan)

A clinical study (pilot study) in Japan initiated in May 2018 for SI-449, an adhesion barrier for use in surgery, is progressing steadily, enrollment of subjects was completed in April 2019, and the Company is currently conducting follow-up observation. In the study, the Company will confirm the utility and safety of SI-449 and exploratively examine its efficacy.

SI-449 is a 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. SI-449 consists of substances naturally present in the body, including the cross-linking agent, and is thought to be highly biocompatible. Since SI-449 is a powdered formulation, it adheres well to uneven tissue surfaces, and is thought to offer excellent utility in laparoscopic surgery, a common surgical procedure. Seikagaku will proceed with development of SI-449 with a view to introducing it globally, not only in Japan.

2. Forecasts for Fiscal 2019

Taking into consideration anticipated higher pharmaceutical sales volumes in Japan and overseas and a sales increase from the LAL business as well as the impact of NHI drug price reductions in this fiscal year and yen appreciation, for fiscal 2019, ending March 31, 2020, the Company forecasts net sales of ¥28,250 million, nearly unchanged from the previous fiscal year.

The Company forecasts a 59.1% decrease in operating income year on year to ¥400 million to result from factors including an expected increase in selling, general and administrative expenses accompanying updating of backbone systems, despite an expected decrease in R&D expenses. The Company expects to record milestone royalty income under non-operating income and a gain on sale of investment securities under extraordinary income and forecasts a 19.6% decrease in ordinary income year on year to ¥2,300 million and a 10.9% decrease in net income attributable to owners of the parent to ¥2,000 million.

The Company forecasts R&D expenses of ¥6,800 million, a decrease of 4.9% year on year, and a ratio of R&D expenses to net sales of 24.1%.

Notes: The exchange rate assumption used in the forecast of consolidated financial results for fiscal 2019 is ¥105 to the U.S. dollar.

*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.

3. Issues Facing the Company

Summary of the mid-term management plan (fiscal 2016 to fiscal 2018)

The Company instituted a mid-term management plan covering the three-year period beginning April 2016 as the final step of The Seikagaku Corporation Ten-Year Vision and has pursued four high-priority strategies.

The first high-priority strategy was development of SI-6603 (product name in Japan: HERNICORE), a treatment for lumbar disc herniation. Although it took time to obtain approval, the Company succeeded in the launch of HERNICORE in Japan in August 2018. Since strict requirements for the use of HERNICORE have been set, the Company is paying due attention to promoting appropriate use and ensuring safety and is striving for a phased rollout. In development in the U.S., the Company announced in November 2017 that a Phase III clinical study did not meet its primary endpoint and initiated an additional Phase III clinical study in February 2018. The Company is currently focusing on various measures to increase the probability of success in the additional study.

The second strategy was development of the knee osteoarthritis market.Although U.S. local sales volumes of Gel-One, an intra-articular single-injection viscosupplement increased, the market environment has become increasingly difficult, and the growth rate fell short of the target. The Company worked to expand into new markets with the objective of maximizing the value of single-injection products and in March 2019 introduced

HyLink, an intra-articular viscosupplement for the treatment of knee osteoarthritis, in Italy. By actively making product modifications to meet user needs, the Company maintained the deliveries to medical institutions of ARTZ, a joint function improving agent sold in Japan. However, the Company's sales declined sharply, reflecting the impact of a substantial price decrease accompanying drastic reform of the NHI drug price system.

Development in Japan of SI-613, a treatment for osteoarthritis and enthesopathy being developed as a next-generation product, has reached the Phase III clinical study stage, and the Company is conducting three trials. Since positive results were obtained in February 2019 in the main study, a confirmatory study on the knee joint, the Company aims to file an application for manufacturing and marketing approval in the first half of 2020 following consideration of the results from the other two studies. The Company concluded an agreement with Ono Pharmaceutical Co., Ltd. on co-development and marketing collaboration in Japan on SI-613 in September 2017 and plans to receive milestone royalties in accordance with future progress in development and marketing.

The third strategy was enhancement of the development pipeline. In May 2018, the Company initiated a clinical study in Japan for SI-449, an adhesion barrier, adding a new theme to the development pipeline. The Company is developing SI-449 with a view to introducing it globally, not only in Japan. Other themes are progressing toward advancement to the clinical development stage.

The fourth strategy was pursuit of an optimal production and quality control system. To strengthen control systems compliant with global standards, including for existing products, the Company upgraded manufacturing facilities and introduced a new quality control system. Furthermore, the Company engaged the services of expert consultants at the Takahagi Plant and Kurihama Plant and implemented operational improvements to boost production efficiency and product cost reduction measures involving cutting of various costs, achieving a certain level of results.

The Company has achieved results in regard to "achieving the ten-year vision and making a further leap forward," the key concept set out in the previous mid-term management plan. Successes include the launch of HERNICORE in Japan, progress with new drug development, including SI-613, and growth of the LAL business. On the other hand, responding to environmental changes, such as drastic reform of the drug price system in Japan, a factor contributing to deterioration of profitability in the pharmaceuticals business, and intensification of competition in overseas markets, is a matter of urgent importance.

Outline of the next mid-term management plan

The business environment facing the pharmaceutical industry is likely to become even more difficult, and securing an earnings foundation will be an urgent task. For this reason, in the pharmaceuticals business, Seikagaku's core business, the Company will devote every effort to rapidly and reliably ensure the success of SI-6603 (HERNICORE) and SI-613 as pillars of the business. In the LAL business, the Company will accelerate expansion into the worldwide market of endotoxin-detecting reagents utilizing gene recombination technology. The Company will also make strategic moves to diversify its earnings model, unconstrained by Seikagaku's traditional business model, and will implement rigorous cost reduction with no preconceptions and pursue an agile management strategy that utilizes the financial foundation.

In the area of R&D, the source of growth, the Company will continue to position glycoscience, Seikagaku's area of specialization, at the core of drug discovery and work to enhance the pipeline. Furthermore, the Company will upgrade and expand its basic technologies that utilize glycoscience, including drug delivery systems (DDS) technologies, and increase R&D efficiency by pursuing an open innovation strategy.

The Company plans to announce the next mid-term management plan and numerical targets in November 2019. In view of the possibility that the management plan and numerical targets may change substantially depending on a future review of HERNICORE use requirements (physician requirements and facility requirements) and the SI-613 development trend, we have judged that it is appropriate to make a public announcement once the degree of certainty has increased.

4. Dividend Policy

Seikagaku regards creating shareholder value as an important management priority and aims to enhance shareholder returns and to realize sustained growth through well-balanced business investment in R&D, production system maintenance, and other areas.

Seikagaku's policy on shareholder returns is to aim for stable and continuous dividends in terms of a medium-to-long-term perspective and to continue paying an annual dividend of ¥26 per share. Seikagaku will also consider purchases of treasury stock, as appropriate, taking into account future business development and the total return ratio.

The Company is currently formulating the next mid-term management plan and is considering the dividend policy. The Company plans to announce the next mid-term management plan in November 2019.

#######