# SEIKAGAKU CORPORATION

# Consolidated Financial Results (Japan GAAP) (Summary) for the Fiscal 2016 (Year Ended March 31, 2017)

Listed exchanges: Tokyo Stock Exchange (First Section)

Stock code number: 4548

URL: http://www.seikagaku.co.jp/english/

Date of ordinary general meeting of shareholders (Planned): June 20, 2017

Date of dividend payment (Planned): June 21, 2017

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

# 1. Consolidated Financial Results for the Fiscal 2016 (from April 1, 2016 to March 31, 2017)

#### (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 2016	29,589	(4.4)	1,282	(40.2)	2,477	(29.2)	1,787	(30.7)
Fiscal 2015	30,962	4.9	2,144	(10.0)	3,500	(12.7)	2,578	(29.4)

(Note) Comprehensive income:

Fiscal 2016: 2,638 million yen [ 198.8% ] Fiscal 2015: 883 million yen [ (87.6% ) ]

	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 2016	31.55	-	2.5	3.1	4.3	
Fiscal 2015	45.39	-	3.7	4.3	6.9	

# (2) Consolidated Financial Position

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	Total assets	Total equity	Equity ratio	Total equity per share				
	Millions of Yen	Millions of Yen	%	Yen				
Fiscal 2016	80,048	70,646	88.3	1,248.07				
Fiscal 2015	80,218	69,815	87.0	1,229.05				

(Reference) Shareholders' Equity:

Fiscal 2016: 70,646 million yen Fiscal 2015: 69,815 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 2016	4,885	(3,502)	(2,282)	8,460
Fiscal 2015	5,595	(3,416)	(1,947)	9,494

#### 2. Dividends

	Dividends per share						
	1 <sup>st</sup> Quarter	2 <sup>nd</sup> Quarter 3 <sup>rd</sup> Quarter		Fiscal Year-end	Annual		
	Yen	Yen	Yen	Yen	Yen		
Fiscal 2015	-	13.00	-	13.00	26.00		
Fiscal 2016	-	13.00	-	18.00	31.00		
Fiscal 2017 (Forecast)	•	13.00	-	13.00	26.00		

(Note) Breakdown of Year-end dividend for Fiscal 2016:

Ordinary dividend: ¥13.00 Commemorative dividend: ¥5.00

	Total dividend payments	Dividend payout ratio	Dividends as a percentage of	
	(Annual)	(Consolidated)	total equity (Consolidated)	
	Millions of Yen	%	%	
Fiscal 2015	1,476	57.3	2.1	
Fiscal 2016	1,754	98.3	2.5	
Fiscal 2017 (Forecast)		54.6		

# 3. Forecast of Consolidated Financial Results for Fiscal 2017 (from April 1, 2017 to March 31, 2018)

(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 2017	30,300	2.4	1,500	17.0	3,750	51.4	2,700	51.0	47.65

#### \* 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)
- (b) Number of treasury stock at the end of the period
- (c) Average number of shares issued during the period

As of March 31, 2017	56,814,093 shares	As of March 31, 2016	58,584,093 shares
As of March 31, 2017	209,561 shares	As of March 31, 2016	1,779,510 shares
Fiscal 2016	56,662,884 shares	Fiscal 2015	56,804,766 shares

# (Reference) Non-Consolidated Financial Results

Non-Consolidated Financial Results for Fiscal 2016 (from April 1, 2016 to March 31, 2017)

# (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 2016	25,460	(5.1)	293	(75.4)	1,487	(41.8)	1,165	(41.7)
Fiscal 2015	26,824	3.2	1,195	(20.8)	2,553	(18.8)	2,000	(34.6)

	Net income per share	Diluted net income per share
	Yen	Yen
Fiscal 2016	20.58	1
Fiscal 2015	35.22	-

# (2) Non-Consolidated Financial Position

	Total assets	Total Equity	Equity ratio	Total Equity per share	
	Millions of Yen	Millions of Yen	%	Yen	
Fiscal 2016	76,717	68,020	88.7	1,201.68	
Fiscal 2015	77,447	68,103	87.9	1,198.90	

(Reference) Shareholders' Equity:

Fiscal 2016: 68,020 million yen Fiscal 2015: 68,103 million yen

#### \*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.

<sup>\*</sup>This financial reports are not subject to audit.

#### 1. Results of Operations

# (1) Analysis of Results of Operations

# Results of operations for the current fiscal year

In the fiscal year ended March 31, 2017 (fiscal 2016), net sales were ¥29,589 million, down 4.4% year on year. The result is attributable to the impact of yen appreciation and National Health Insurance (NHI) drug price reductions in Japan, despite higher sales volumes of pharmaceuticals in Japan, Gel-One in the U.S., and the LAL business overseas.

With regard to earnings, operating income fell 40.2% year on year to \(\frac{\pmathbf{\frac{4}}}{1,282}\) million, reflecting the sales decrease and an increase in the cost of sales ratio for reasons including (NHI) drug price reductions and one-time factors associated with the introduction of new syringes for ARTZ, a joint function improving agent, despite a decrease in selling, general and administrative expenses, mainly R&D expenses. Ordinary income fell 29.2% year on year to \(\frac{\pmathbf{2}}{2,477}\) million, and net income attributable to owners of parent fell 30.7% year on year to \(\frac{\pmathbf{1}}{1,787}\) million, reflecting an increase in royalty income, despite a decrease in gain on sale of investment securities.

#### 1) Net sales by segment

#### **Pharmaceutical Business**

#### - Domestic Pharmaceuticals (¥16,268 million, down 3.9% year on year)

In a flat overall market, deliveries to medical institutions of ARTZ, a joint function improving agent, increased slightly due to strengthening of sales promotion activities accompanying the introduction of new syringes in April 2016. The Company's sales to the sales partner decreased as a result of the impact of NHI drug price reductions.

Deliveries to medical institutions and market share of the OPEGAN series, ophthalmic surgical aids, increased as market penetration of SHELLGAN, launched in July 2016, steadily progressed as a result of active sales measures. The Company's sales to the sales partner also rose, compensating for the impact of NHI drug price reductions.

The Company's sales of MucoUp, a surgical aid for endoscopic mucosal resection, were at nearly the prior-year level due to a one-time increase in shipments accompanying a change in sales partner in April 2016.

#### - Overseas Pharmaceuticals (¥6,771 million, down 7.2% year on year)

U.S. sales of Gel-One, a single-injection joint function improving agent, were strong. The Company's sales to the sales partner fell slightly due to the impact of yen appreciation and a decline in local selling prices, despite an increase in shipment volumes.

U.S. sales of SUPARTZ FX, a 5-injection joint function improving agent, fell only slightly amid increasingly fierce competition due to factors such as the introduction of other new multiple injection products. The Company's sales to the sales partner decreased due to the impact of yen appreciation.

The Company's sales of ARTZ to the sales partner in China (P.R.C.) decreased due to a downtrend in sales in the market resulting from the government's price-curbing policy coupled with the impact of yen appreciation.

# - Bulk Products (¥1,111 million, down 13.7% year on year)

Although sales of chondroitin sulfate increased, overall sales declined, reflecting fierce competition in the market for hyaluronic acid.

As a result of these developments, sales from the pharmaceuticals business fell 5.4% year on year to \(\xi 24,152\) million.

#### **LAL Business**

Sales from the LAL business fell 0.1% year on year to ¥5,437 million, due to exchange rate despite higher overseas sales of endotoxin-detecting reagents and other products on a local currency basis.

#### 2) Research and Development Activities

The Company focuses its research and development on glycoscience as its area of specialization and aims to develop as a "Global Category Pharma" that contributes to healthy and fulfilling lives for people around the world. To achieve early and continuous launching of new drugs, which hold the key to future business growth, the Company is strengthening research and development capabilities and working to expand and enhance the glycoscience research network in Japan and overseas.

Total R&D expenses in fiscal 2016 were ¥7,834 million, or 26.5% of net sales, and the number of R&D personnel was 222, or 32.3% of the total number of employees, at the end of March 2017.

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

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

The Company submitted a new drug application (NDA) to the Ministry of Health, Labor and Welfare of Japan in January 2014. The NDA examination concerning quality control in the manufacturing process is ongoing, and the Company will endeavor to obtain marketing approval at an early date.

The Company completed enrollment for a Phase III clinical trial in the U.S. in July 2015, and the trial has reached the follow-up observation stage. Follow-up observation in the open-label trial in Europe and the U.S., mainly for the purpose of safety evaluation, has been completed in March 2017 and the Company is now compiling data. The Company entered into a license agreement for the exclusive development and commercialization rights to SI-6603 worldwide, excluding Japan, with Ferring Pharmaceuticals, which has its headquarters in Switzerland, in August 2016.

SI-6603, an enzyme named condoliase, is thought to be effective in reducing pressure on the nerve that is the cause of lumbar disc herniation pain. A single injection of SI-6603 into the lumbar disc is expected to be as effective as surgical removal.

#### SI-613 (treatment of osteoarthritis: developed in Japan)

Clinically effective results were confirmed in Phase II clinical trials conducted for the indication of knee osteoarthritis. As a result, the Company initiated a Phase III clinical development in February 2017 and will conduct a verification study targeting at knee joint, the clinical studies for other joints (hip, ankle, elbow and shoulder) and a long-term study with a main purpose for safety evaluation. The Company reached a basic agreement related to co-development and marketing collaboration on SI-613 in Japan with Ono Pharmaceutical Co., Ltd. in May 2017 and will further discuss to sign a definitive agreement on SI-613...

SI-613 is a formulation in which hyaluronic acid and a non-steroidal anti-inflammatory drug (NSAID) are chemically bound using a Seikagaku's own proprietary technology. Combining the pain relief and anti-inflammatory effect of an NSAID designed for sustained release with the joint function improving effect of hyaluronic acid is expected to provide prompt and long-lasting relief of the intense pain and inflammation associated with osteoarthritis. Further, the Company will aim to expand the target patient population by making possible administration to joints other than the knee.

#### SI-614 (treatment of 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 a Seikagaku's own proprietary technology. Ocular instillation of SI-614 in patients with dry eye is expected to protect the ocular surface and promote corneal wound healing.

#### (2) Forecasts for Fiscal 2017

The Company forecasts a 2.4% increase in net sales year on year to ¥30,300 million in fiscal 2017, ending March 31, 2018, as a result of expected sales increases for Gel-One and the overseas LAL business.

The Company forecasts a 17.0% increase in operating income year on year, to \\(\frac{\pmathbf{\frac{4}}}{1,500}\) million, due to the projected sales increase and improvement in the cost of sales ratio, despite expected increases in R&D expenses for pipeline projects such as SI-613, joint function improving agent, and selling, general and administrative expenses coupled with boosted sales activities at the U.S. subsidiary. The Company expects a increase in royalty income in non-operating income and forecasts a 51.4% increase in ordinary income year on year to \\(\frac{\pmathbf{2}}{3,750}\) million and a 51.0% increase in net income attributable to owners of the parent to \\(\frac{\pmathbf{2}}{2,700}\) million.

The Company forecasts R&D expenses of ¥8,350 million, an increase of 6.6% year on year, and a ratio of R&D expenses to net sales of 27.6%.

\* Although the Company submitted NDA in Japan for SI-6603, for treatment of lumbar disc herniation, SI-6603 has not been included in the sales forecast. The NDA examination concerning quality control in the manufacturing process is ongoing, and the Company will endeavor to obtain marketing approval at an early date.

- \* The exchange rate assumption used in the forecast of consolidated business results for fiscal 2017 is ¥108 to the U.S. dollar.
- \*Disclaimer regarding forward-looking information including appropriate use of forecasted financial results

The forecasted statement shown in these materials is 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) 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.

Seikagaku will mark the 70th anniversary of its founding on June 2, 2017. For the purpose of expressing gratitude to the shareholders, Seikagaku plans pay a total year-end dividend of ¥18 per share, to consist of a 70th anniversary commemorative dividend of ¥5 and an ordinary dividend of ¥13 (to be proposed at the 71st Ordinary General Meeting of Shareholders scheduled to be held on June 20, 2017). This will result in an annual dividend of ¥31 per share, including the interim dividend of ¥13 per share.

#### 2. Medium-to-Long-term Business Strategy

#### (1) Medium-to-Long-term Business Strategy and Issues Facing the Seikagaku Group

The pharmaceutical industry is in a period of great transformation due to growing pricing pressures on medical services, large-scale realignment of pharmaceutical companies across national borders, and technological innovation in drug discovery research accompanied by more intense competition in new drug development.

Responding to this business environment, in March 2009 Seikagaku established the Seikagaku Corporation Ten-Year Vision with the aim of developing as a "Global Category Pharma."

# Seikagaku Corporation Ten-Year Vision

- Launch new drugs (including medical devices) on a consistent basis and cultivate the capability to open up a new market every three years that has the potential to become a mainstay business.
- Focus research and development on glycoscience and sustain steady growth as a "Global Category Pharma" that establishes global competitiveness.

# Outline of the mid-term management plan (Fiscal 2016 to Fiscal 2018)

In light of the accomplishments and the issues that remain under the previous management plan, Seikagaku has formulated a mid-term management plan covering the three-year period beginning in April 2016 as the final step toward achieving the Ten-Year Vision. Under the new plan, Seikagaku will undertake further sales expansion in the U.S., a key market, and aim to launch in Japan and to obtain approval in the U.S. for SI-6603, treatment for lumbar disc herniation, and to enter new markets for existing products. To support these actions, Seikagaku will also strengthen production and quality control systems compliant with global standards.

Furthermore, Seikagaku will establish core technologies to enhance the drug discovery and drug cultivation pipeline that will lead to next-generation leap and will build a powerful research and development organization in preparation for further growth.

# **Key Concepts**

- "ACT for the Vision" Achieving the Ten-Year Vision and Making a Further Leap Forward. Active spirit, Creative mind, Takeoff
- Overcome severe environment in the business, achieve the Ten-Year Vision, and survive as a "Global Category Pharma."

#### **High-Priority Strategies**

(1) Preparing for launch of SI-6603, a treatment for lumbar disc herniation

- 1) Proceed with a launch in Japan and realize sales expansion in accordance with appropriate use.
- 2) Aim for commercialization in the U.S., which is potential big market.
- (2) Powering up as a leader in the knee osteoarthritis market
  - 1) Promote sales expansion in the U.S. and new market development for growth driver Gel-One.
  - 2) Maintain sales volumes of ARTZ in Japan through product improvements.
  - 3) Proceed with development of SI-613, a joint function improving agent positioned as a next generation product.
- (3) Enhancement of the development pipeline
  - 1) Maintain basic technologies superior to those of competitors in the field of glycoscience, accelerate exploratory research, and continuously originate and create development themes.
  - 2) Steadily advance the stages of projects in the pipeline by enhancing clinical development capabilities.
- (4) Pursuit of an optimal production system
  - 1) Ensure a stable supply of products and realize cost reductions by implementing further production efficiency improvements.
  - 2) Strengthen production and quality control systems compliant with global standards and capable of rapidly responding to regulatory trends.

#### Progress with the Mid-term Management Plan in Fiscal 2016

Gel-One, a single-injection joint function improving agent for the U.S. positioned as a growth driver, is seeing a steady increase in local sales volume due to the market development efforts of Zimmer Biomet, the sales partner. In November 2016 Seikagaku entered into an agreement of exclusive distributorship in the U.S. for VISCO-3, a three-injection joint function improving agent, with Zimmer Biomet. As a result, Seikagaku will have a line of products with three different varieties of injections formats, including SUPARTZ FX, a five-injection joint function improving agent sold through Bioventus. The Company will continue efforts to strengthen the presence of Seikagaku products in the U.S., a key region in the growth strategy.

The market environment for ARTZ, a joint function improving agent sold in Japan, is becoming increasingly difficult due to the impact of periodically implemented NHI drug price reductions coupled with flat volume growth in the market as a whole. In these circumstances, sales volume is increasing, partly as a result of the impact of the introduction of new syringes in April 2016. With regard to the OPEGAN series of ophthalmic surgical aids, market penetration of SHELLGAN, launched in July 2016 for the purpose of strengthening the product line, is proceeding steadily. The Company will continue efforts to raise product awareness and increase the number of prescriptions.

In the area of new drug development, the NDA examination concerning quality control in the manufacturing process for SI-6603, treatment for lumbar disc herniation, is ongoing, and the Company will endeavor to obtain marketing approval at an early date. With a view to overseas business development for SI-6603, in August 2016 Seikagaku entered into a licensing agreement for the exclusive development and commercialization rights to SI-6603 worldwide, excluding Japan, with Ferring Pharmaceuticals, which has its headquarters located in Switzerland.

Seikagaku initiated a Phase III clinical trial in Japan for SI-613, a new joint function improving agent targeted for global business development, in February 2017. The Company concluded a basic agreement related to co-development and marketing collaboration on SI-613 in Japan with Ono Pharmaceutical Co., Ltd. in May 2017 and will further discuss to sign a definitive agreement on SI-613.

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