## SEIKAGAKU CORPORATION

# Consolidated Financial Results (Summary) for Fiscal 2010 (Year Ended March 31, 2011)

Stock code number: 4548 Listed exchanges: Tokyo

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

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

## 1. Consolidated Financial Results for Fiscal 2010 (from April 1, 2010 to March 31, 2011)

## (1) Consolidated Financial Results

(Percentages indicate changes from in the prior fiscal year.)

	Net	Net sales		g income	Ordinary income		Net income	
	Millions of yen	%	Millions of Yen	%	Millions of yen	%	Millions of yen	%
Fiscal 2010	27,117	(1.8)	3,533	(30.9)	4,159	(18.7)	2,451	(31.4)
Fiscal 2009	27,617	1.5	5,110	8.1	5,114	0.4	3,575	12.6

Notes: Comprehensive income:

Fiscal 2010: ¥2,101 million (-53.7%) Fiscal 2009: ¥4,538 million (-%)

	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 2010	43.16	-	4.4	6.6	13.0	
Fiscal 2009	62.94	-	6.6	8.5	18.5	

Reference: Equity in earnings of subsidiaries and affiliates accounted for by the equity method:

Fiscal 2010: -Fiscal 2009: -

## (2) Consolidated Financial Position

	Total assets	Total equity	Total equity ratio	Total equity per share	
	Millions of yen	Millions of yen	%	Yen	
Fiscal 2010	62,684	56,106	89.5	987.67	
Fiscal 2009	62,734	55,426	88.4	975.68	

Reference: Shareholders' equity:

Fiscal 2010: ¥56,106 million Fiscal 2009: ¥55,426 million

## (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 year	
	Millions of yen	Millions of yen	Millions of yen	Millions of yen	
Fiscal 2010	4,819	(4,658)	(1,653)	7,692	
Fiscal 2009	8,455	(4,249)	(1,622)	9,367	

#### 2. Dividends

	Dividends per share					
(Record date)	1st Quarter	2nd Quarter	3rd Quarter	Year-end	Annual	
	Yen	Yen	Yen	Yen	Yen	
Fiscal 2009	-	12.50	-	12.50	25.00	
Fiscal 2010	-	12.50	-	12.50	25.00	
Fiscal 2011		12.50		12.50	25.00	
(Forecast)	-	12.50	-	12.50	25.00	

	Total dividend payments	Dividend payout ratio	Dividends as a percentage of	
	(Annual)	(Consolidated)	total equity (Consolidated)	
(Record date)	Millions of yen	%	%	
Fiscal 2009	1,420	39.7	2.6	
Fiscal 2010	1,420	57.9	2.5	
Fiscal 2011		43.0		
(Forecast)		43.0		

## **3. Forecast of Consolidated Results for Fiscal Year 2011** (from April 1, 2011 to March 31, 2012)

(Percentages indicate changes from in the prior fiscal year.)

	Net s	ales	Operating income		Ordinary income		Net income		Net income per share
	Millions of yen	%	Yen						
First six-month of fiscal 2011	14,200	2.3	2,300	27.8	2,400	39.7	1,500	27.3	26.40
Fiscal 2011	28,000	3.3	4,800	35.9	5,100	22.6	3,300	34.6	58.09

## 4. Others

- (1) Changes in the state of material subsidiaries during the period under review: No
- (2) Changes in principles, procedures, and presentation methods, etc., related to the consolidated financial statements
- (a) Changes related to revisions in accounting principles: Yes
- (b) Changes aside from those in (a) above: Yes
- (3) Number of common shares issued
- (a) Total number of shares issued at the end of the period (including treasury stock)

As of March 31, 2011	58,584,093 shares
As of March 31, 2010	58,584,093 shares

(b) Number of shares in treasury at the end of the period

As of March 31, 2011	1,776,565shares
As of March 31, 2010	1,776,416 shares

(c) Average number of shares during the period

As of March 31, 2011	56,807,663 shares
As of March 31, 2010	56,808,156 shares

#### (Reference) Non-Consolidated Financial Results

Non-Consolidated Financial Results for Fiscal 2010 (from April 1, 2010 to March 31, 2011)

#### (1) Non-Consolidated Financial Results

(Percentages indicate changes from in 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 2010	22,309	(0.9)	2,370	(37.9)	3,609	(17.9)	1,899	(41.3)
Fiscal 2009	22,510	2.8	3,819	5.7	4,397	7.8	3,234	26.4

	Net income per share	Diluted net income per share
	Yen	Yen
Fiscal 2010	33.44	-
Fiscal 2009	56.94	-

### (2) Non-Consolidated Financial Position

	Total assets	Total equity	Total equity ratio	Total equity per share
	Millions of yen	Millions of yen	%	Yen
Fiscal 2010	63,193	56,490	89.4	994.42
Fiscal 2009	63,567	56,057	88.2	986.80

Reference: Shareholders' equity

Fiscal 2010: ¥56,490 million Fiscal 2009: ¥56,057 million

#### \*Note regarding implementation of audit procedures

This summary of financial results is not subject to the audit procedures in accordance with the Financial Instruments and Exchange Act.

At the time when this summary of financial results was released, the audit procedures were in progress for the financial statements in accordance with the Financial Instruments and Exchange Act.

#### \*Disclaimer regarding forward-looking information including appropriate use of forecasted financial results

The forecasted statement 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.

The forecast does not take into account the impact of the Great East Japan Earthquake other than estimable extraordinary losses.

#### 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, 2011 (fiscal 2010), the business environment for pharmaceuticals remained severe. In Japan, measures to curb medical expenses continued, including an NHI drug price reduction in April and promotion of the use of generic drugs. Overseas, efforts to limit medical spending such as tightening of insurance reimbursement criteria continued, and standards for new drug approval are also becoming much stricter.

In these circumstances, net sales for fiscal 2010 fell 1.8% year on year to ¥27,117 million. While pharmaceuticals in Japan rose due to a sales volume increase of ARTZ®, net sales declined because of lower sales volumes to the U.S. and the impact of yen appreciation. Another factor for this decline was a change in accounting policy, decided in fiscal 2010, by which the recording of milestone royalty income is classified as non-operating income rather than as net sales.

Although an increase in pharmaceutical sales volume in Japan compensated for the impact of the drug price reduction, operating income fell 30.9% year on year to ¥3,533 million income. Factors influencing this result included the impact of yen appreciation, a sharp increase in R&D expenses accompanying posting in full of SI-6603 clinical trials expenses accompanying with their completion in Japan and a decline in profit commensurate with the sales decrease due to the above-mentioned change in accounting policy. Ordinary income fell 18.7% to ¥4,159 million, due to the above-mentioned recording of milestone royalty income under non-operating income. Net income fell 31.4% to ¥2,451 million as a result of the recording of extraordinary losses of ¥984 million. Major items in these losses were the cost of restoring damage to facilities at the Takahagi Plant (Takahagi City, Ibaraki Prefecture) by the Great East Japan Earthquake and impairment loss on valuation of land owned by the Company and rented to Sanriku Kakou Corporation (a subsidiary in Kesennuma City, Miyagi Prefecture), which was severely damaged by the resulting tsunami.

The Great East Japan Earthquake caused the damage to the Takahagi Plant, which produces pharmaceuticals and Sanriku Kakou, which processes raw materials for the production of chondroitin sulfate. As for the Takahagi Plant, no disruption to the Company's shipment plan or to the stable supply of pharmaceuticals occurred, because, we were able to resume shipment of products in inventory in mid-March. Furthermore, since production facility damage was rather limited, the Takahagi Plant restored its production systems to normal operation by the end of April, following the restoration of public utility services in the area. On the other hand, Sanriku Kakou, incurred extensive damage from the tsunami. The resumption of business operations is uncertain at this time. But, the disaster had no direct impact on production or shipments of chondroitin sulfate in fiscal 2010.

### 1) Net Sales by Segment

## **Pharmaceuticals**

#### - Domestic

The market in Japan for ARTZ<sup>®</sup>, an injectable treatment for osteoarthritis pain of the knee, continued to expand. The market growth is partly attributable to an increase in the aged population and to patient education activities targeting knee osteoarthritis sufferers conducted together with sales partner Kaken Pharmaceutical Co., Ltd. Focused sales expansion activities that capitalized on the brand strength of an original drug and the introduction of a plastic syringe that meets physician and patient needs contributed to a market share increase for ARTZ<sup>®</sup>, and sales rose as higher deliveries to medical institutions more than offset the impact on sales of the NHI drug price reduction.

Sales of the ophthalmic surgery aid OPEGAN® fell year on year. Although continued sales promotion activities focused on target patients, conducted in collaboration with sales partner Santen Pharmaceutical Co., Ltd., led to an increase in deliveries to medical institutions, the higher unit sales did not fully offset the impact of the NHI reimbursement price reduction.

Sales of MucoUp<sup>®</sup>, a surgical aid for use in endoscopic mucosal resection, were also higher in response to market-building initiatives, such as workshops for surgeons on endoscopic surgical techniques held in cooperation with our sales partner, Johnson & Johnson K.K.

#### - Overseas

The Company's export sales to the U.S. of SUPARTZ<sup>®</sup>, the product name of ARTZ<sup>®</sup>, in the U.S., decreased year on year. Although price maintenance efforts stemmed a decline in local selling prices, unit sales in the U.S. fell, due to factors including tightening of insurance reimbursements by some private insurance companies. A build-up of distributor inventories at the end of fiscal 2009 and the impact of yen appreciation also adversely affected sales. Meanwhile, export sales to China continued to rise. ARTZ<sup>®</sup> enjoys an excellent reputation in China for high quality and proven performance around the world, particularly among medical institutions in major cities.

As a result, sales of pharmaceuticals fell 1.0% year on year to \(\frac{\pma}{2}\)1,184 million.

#### **Fine Chemicals**

Sales of hyaluronic acid increased, and endotoxin assay reagents used in quality control showed solid performance in overseas markets. However, due to yen appreciation and lower sales of research reagents in Japan, sales of fine chemicals fell 4.5% year on year to ¥5,933 million.

#### **About Segment Information**

The Company has applied "Revised Accounting Standard for Disclosures about Segments of an Enterprise and Related information" (ASBJ Statement No.17) and "Application Guideline for Accounting Standards for Disclosure of Segment Information, etc." (Corporate Accounting Standards Application Guideline No. 20) beginning in the first quarter of the fiscal year ended March 31, 2011. As a result, the information in Net Sales by Segment section above has been classified into two segments: Pharmaceuticals and Fine Chemicals. A breakdown of the net sales included in the two segments follows.

#### Pharmaceuticals

Domestic: Net sales related to the domestic pharmaceuticals business

Overseas: Net sales related to the pharmaceuticals export business

#### Fine Chemicals

Research reagents and diagnostics: Net sales related to the research reagents and diagnostics business

Bulk products: Net sales related to the bulk products business, health food raw materials business, and other businesses

## 2) Selling, general and administrative expenses

Selling, general and administrative expenses in fiscal 2010 rose 9.1% year on year to \$13,103 million, principally due to higher R&D expenses. R&D expenses in fiscal 2010 rose 21.9% year on year to \$6,723 million, and the ratio of R&D expenses to net sales was 24.8%.

## 3) Other income and expenses

Other income in fiscal 2010 rose 110.4% year on year to \$1,043 million. The increase is mainly attributable to the recording of \$567 million in milestone royalty income.

Other expenses fell 15.2% year on year to ¥417 million. The decrease is mainly attributable to a ¥71 million decrease in foreign exchange loss.

## 4) Extraordinary gain and loss

The Company recorded extraordinary losses of ¥984 million in fiscal 2010. (There were no extraordinary losses in fiscal 2009.) The principal item was a loss of ¥932 million for restoration costs for facilities, impairment loss on valuation of land, and other costs associated with the Great East Japan Earthquake. The losses also include ¥51 million, the impact of accounting for asset retirement obligations, which was applied in fiscal 2010.

#### 5) Research and development activities

Progress with research and development activities is described below.

• Gel-One<sup>®</sup> (single-injection treatment for osteoarthritis pain of the knee; development code: Gel-200)

The Company received U.S. Food and Drug Administration (FDA) approval for Gel-One<sup>®</sup> as a medical device in March 2011. The main ingredient of Gel-One<sup>®</sup> is a cross-linked hyaluronate produced using a cross-linking technology developed by Seikagaku. It provides pain relief from a single injection. A 2011 launch is planned.

• SI-602 (additional indication for treatment of shoulder osteoarthritis for SUPARTZ® in the U.S.)

Although the Company submitted a premarket approval application (PMA) for this additional indication for SUPARTZ® in September 2009, we withdrew the application in March 2011 as the FDA requested clinical trials.

• SI-6603 (treatment for lumbar disc herniation)

Follow-up after administration in a Phase II/III clinical trial in Japan was completed in August 2010. In December 2010, significant improvement in leg pain 13 weeks after administration in comparison with a placebo, the primary endpoint of this trial, was demonstrated. Also it was well tolerated with no major safety concerns. In light of the favorable trial results, the Company plans to submit a PMA in the second half of 2011. We are also focusing on progress with Phase II trials underway in the U.S.

• SI-615 (rheumatoid arthritis treatment: in-licensed)

A Phase I clinical trial of a single-drug oral dose has been completed in Japan. Since originator Can-Fite BioPharma Ltd. is currently conducting a single-drug late Phase II trial, the Company plans to consider the future development policy while observing the progress of this trial.

• SI-636 (inflammatory disease treatment: in-licensed)

Originator BioTie Therapies Corporation reported in January 2010 that safety and tolerability had been confirmed in a Phase I repeated-dose study for rheumatoid arthritis conducted in Europe. SI-636 is in the pre-clinical stage in Japan, and the Company plans to consider the future development policy, taking into consideration the progress in clinical development in Europe.

In addition, the Company is developing two in-house themes, one for ophthalmic disease and another for arthritis, both with the aim of commencing clinical trials at an early date.

#### **Forecasts for Fiscal 2011**

The Company forecasts a 3.3% increase in net sales to ¥28,000 million in fiscal 2011 ending March 31, 2012. Sales of pharmaceuticals will increase due to continued steady sales performance of ARTZ<sup>®</sup> in Japan. Also, overseas sales will increase because of local sales increases in China and Italy. On the other hand, fine chemical sales will be lowered due to the termination of sales of research reagents in September 2011, despite an anticipated increase in overseas sales.

We forecast a 35.9% increase in operating income to  $\$4,\!800$  million. We anticipate a sales volume increase for pharmaceuticals, lower product costs due to factors including a decrease in depreciation on the No. 4 Production Building at the Takahagi Plant, and lower R&D expenses following a temporary increase in fiscal 2010 for SI-6603 clinical trials in Japan.

We forecast a 22.6% increase in ordinary income to  $\$5,\!100$  million as a result of lower milestone royalty income and a 34.6% increase in net income to  $\$3,\!300$  million due to decreases in extraordinary losses from the earthquake and other items.

We forecast R&D expenses of ¥5,900 million, a decrease of 11.6% year on year, and a ratio of R&D expenses to net sales of 21.1%.

\*The exchange rate assumption used in the forecast of consolidated business results for the fiscal 2011 is

¥83 to the US dollar.

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. The forecast does not take into account the impact of The Great East Japan Earthquake other than estimable extraordinary losses.