# Financial Results for the First Half of Fiscal Year 2012 (April 1, 2012 - September 30, 2012)

**Exploring the Innovative Promise of Glycoscience** 



SEIKAGAKU CORPORATION

(TSE:4548)

http://www.ehiza.jp

## **Financial Results for First Half**

(Millions of Yen)

				,
	FY2012 1H Results	vs. FY2011 1H Results	vs. 5/10 Initial Forecast for 1H	vs. 9/26 Revised Forecast for 1H
Net Sales	13,239	<b>-556</b> (-4.0%)	+ <b>39</b> (+0.3%)	<b>-10</b> (-0.1%)
Operating Income	1,324	<b>-1,888</b> (-58.8%)	+ <b>224</b> (+20.4%)	+ <b>24</b> (+1.9%)
Ordinary Income	1,781	<b>-1,402</b> (-44.1%)	+581 (+48.4%)	+ <b>31</b> (+1.8%)
Net Income	1,266	<b>-843</b> (-40.0%)	+ <b>466</b> (+58.3%)	+ <b>16</b> (+1.3%)
R&D Expenses	3,412	+ <b>989</b> (+40.8%)	+112 (+3.4%)	-
R&D Expenses Ratio (to Net Sales)	25.8%	+8.2pt	+0.8pt	-
Net Income Per Share	¥22.29	-¥14.84	+¥8.21	+¥0.29
Average Exchange Rate (¥/1US\$ SEIKAGAKU CORPORATION	<b></b>	¥79.81	¥81.00	¥79.39

## Net Sales for 1H of FY2012 (compared with FY2011/1H)

(Millions of Yen)

## Net Sales: ¥13,239 (-¥556 / -4.0%)

#### [Pharmaceuticals: ¥11,453(-¥186)]

#### • Japan (-¥297)

- ARTZ<sup>®</sup> : Higher deliveries to medical institutions and market share, with ARTZ<sup>®</sup> as the market driver Seikagaku sales down slightly due to NHI drug price reductions
- OPEGAN<sup>®</sup>: Higher deliveries to medical institutions, but continuing intensified competition Seikagaku sales down due to the impact of NHI drug price reductions and inventory adjustments by sales partner
- MucoUp<sup>®</sup>: Seikagaku sales increase due to a rise in the number of endoscopic surgeries

Emdogain Gel® : Sales discontinued at the end of December 2011

#### •Overseas(+¥132)

United States: Slight increase in local sales. Increase in export sales partly attributable to an inventory buildup implemented by sales partner

China: Continued strong local sales and export sales

• Bulk Products (-¥22): Low level of chondroitin sulfate shipments

[LAL: ¥1,785(-¥370)] Decrease due to discontinuation of the research reagents business

Point: Decrease in sales due to the impact of NHI drug price reductions and discontinuation of the research reagents business, despite higher sales volumes of ARTZ® in Japan and overseas.



## Incomes for 1H of FY2012 (compared with FY2011/1H)

## **Operating Income: ¥1,324(-¥1,888 / -58.8%)** (Millions of yen)

## [Cost of Sales (-¥98)]

Decrease due to discontinuation of the research reagents business and lower depreciation of the No. 4 Production Building at the Takahagi Plant, despite sales volume increases of ARTZ<sup>®</sup> in Japan and overseas \*Cost of sales ratio: 36.5% (+0.7 pt)

## [SG&A expenses (+¥1,430)]

- R&D expenses: ¥3,412 (+¥989): Increase related to progress with development themes such as SI-614

- Increase in Gel-One lawsuit expenses

## Net Income: ¥1,266(-¥843/ -40.0%)

[ Non-Operating Income/Expenses (+¥485) ] Occurrence of royalty income

[ Extraordinary losses (-¥71)] Non-recurrence of losses from the earthquake

\*In addition, application of preferential taxation due to designation of the Takahagi Plant as a special district for industrial revitalization

Point: Income decrease attributable to the impact of NHI drug price reductions coupled with increases in R&D expenses related to progress with development themes and Gel-One lawsuit expenses, despite the recording of royalty income

# **Net Sales by Business Segment**

(Millions of Yen)

.AL Bu	siness: 1 <mark>3.5%(-2.1</mark>	lpt)	Segment	Net Sales	vs. Previous Period	Change
			[Pharmaceuticals]	11,453	-186	-1.6%
			Domestic Pharmaceuticals	9,032	-297	-3.2%
Net Sales ¥13,239 mil.			Overseas Pharmaceuticals	1,783	+132	+8.1%
	+13,233 mm.		Bulk Products	636	-22	-3.4%
Pharn	naceuticals: 86.5%	∕₀ (+2.1pt)	[LAL Business]	1,785	-370	-17.2%
Dome	stic Pharmaceuticals:	68.2%	Total	13,239	-556	-4.0%
	eas Pharmaceuticals Products:	4.8%	(Overseas Sales)	2,955	-74	-2.5%
Domestic Sales 77.7%(-0.3pt)				Oversea 22.3% (*	as Sales +0.3pt)	
, D	25%	Note:	50% Due to changes in Se	75 aments from EX		10 1H figures
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## FY2012 1H Results (Compared with Initial Forecast)

(Millions of yen)

## Net Sales: ¥13,239 (+¥39 / +0.3%)

- Pharmaceuticals(+¥153): Volume increases for ARTZ<sup>®</sup> in Japan and overseas to compensate for decline in bulk products
- LAL Business(-¥114): Decrease due to carryover of shipments at the overseas subsidiaries

## **Operating Income:** ¥1,324(+¥224 / +20.4%)

• Cost of sales (approx. -¥250): Deferment of expenses related to plant facilities to the second half

SG&A expenses (approx. +¥50): R&D expenses (+¥112) Forecast: ¥3,300 mil. ⇒ Actual: ¥3,412 mil.

⇒ Increase related to progress with development themes Decrease in other SG&A expenses

## Net Income: ¥1,266(+¥466 / +58.3%)

- Increase in non-operating income: Occurrence of royalty income
- Decrease in corporate tax: Preferential taxation due to designation of the Takahagi Plant as a special district for industrial revitalization

Point: Net sales nearly in line with forecast. Income upward due to deferment of expenses related to plant facilities and the recording of royalty income



## **Overview of Forecast for FY2012**

(Millions of Yen)

	FY2012 Revised Forecast	Initial Forecast	vs. Initial Forecast	FY2011 Results	vs. Previous Year
Net Sales	26,750	26,700	<b>+50</b> (+0.2%)	27,082	<b>-332</b> (-1.2%)
Operating Income	2,700	2,600	<b>+100</b> (+3.8%)	4,617	<b>-1,917</b> (-41.5%)
Ordinary Income	3,550	3,100	<b>+450</b> (+14.5%)	4,770	<b>-1,220</b> (-25.6%)
Net Income	2,700	2,200	<b>+500</b> (+22.7%)	3,270	<b>-570</b> (-17.5%)
R&D Expenses	6,700	6,700	<b>0</b> (0.0%)	5,970	<b>+729</b> (+12.2%)
R&D Expenses Ratio (to Net Sales)	25.0%	25.1%	-0.1pt	22.0%	+3.0pt
Net Income Per Share	¥47.53	¥38.73	+¥8.80	¥57.58	-¥10.05
Average Exchange Rate (¥/1US\$) SEIKAGAKU CORP	$\mp 10.00$	¥81.00		¥79.07	

## Revised FY2012 Forecast (compared with Initial Forecast)

(Millions of yen)

## Net Sales: ¥26,750(+¥50 / +0.2%)

- Domestic pharmaceuticals (approx. -¥50): Decrease in OPEGAN<sup>®</sup>
- Overseas pharmaceuticals (approx. +¥300): Increase due to shipments of Gel-One<sup>®</sup> and a higher export

volume increase to China, despite the impact of yen appreciation

Bulk products (approx. -¥150) and LAL (approx. -¥50)
 \*Impact of yen appreciation on overall net sales (approx. -¥150)

## **Operating Income: ¥2,700(+¥100/ +3.8%)**

- SG&A expenses (approx. -¥150):
- Decrease in SG&A expenses such as Gel-One<sup>®</sup> lawsuit expenses (approx. -¥100)
- No change in R&D expenses from the initial forecast (6,700)

## Net Income: ¥2,700 (+¥500 / +22.7%)

Increase in non-operating incomes: Occurrence of royalty income

Decrease in corporate tax: Preferential taxation due to designation of the Takahagi Plant as a special district for industrial revitalization

Point: Expected slight increase in net sales on shipments of Gel-One<sup>®</sup> and a higher export volume increase to China, despite the impact of yen appreciation. Income revised upward on a decrease in SG&A expenses and the occurrence of royalty income

## Trend in R&D Expenses



development themes and higher depreciation of research facilities.

## **Domestic Sales of ARTZ®** (unit deliveries to medical institutions)



#### FY2012 1H Results (compared with FY2011/1H)

<<Market>>: +3.1%

- Market expansion due to an increase in the aged population and continued implementation of disease awareness campaigns

 $\Rightarrow$  Growth rate at the previous first half of the year level <<ARTZ<sup>®</sup>>>: +5.1%

- Enhanced brand potential as the original product
- Reputation enhancement due to introduction of a plastic syringe product

 $\Rightarrow$  ARTZ<sup>®</sup> is the market driver.

Market share increase 55.5% (up 1.1pt)

FY2012 Full-year Forecasts (year-on-year)

<<Market>>: +5.5%

<<ARTZ<sup>®</sup>>>: +8.0%

- Continuation of marketing activities that take advantage of brand strength
- Increase in prescriptions through measures to commemorate the 25th anniversary of the introduction of ARTZ<sup>®</sup>
  - ⇒ Seek an increase to exceed market growth.

Drug price revisions (effective April 2012) - ARTZ Dispo<sup>®</sup>: ¥1,526 (-6.8%)

- ARTZ DISpo<sup>®</sup>. ¥1,526 (-6.8%) - Industry average: -6.2%



ARTZ®: A joint-function improvement agent with hyaluronic acid as its main ingredien

#### Market Expansion through Disease Awareness Campaigns

Launch of the "Knee Science Institute" website to disseminate awareness surveys and explanations from specialists



# Conduct of a survey concerning knee pain and ways of coping with it



Broadcast of a TV program to explain reasons for knee pain and introduce prevention and treatment methods





## **Overseas Pharmaceuticals** (value basis)



#### FY2012 1H Results +8.1% (compared with FY2011/1H)

<<United States>>

- SUPARTZ<sup>®</sup> local sales: +0.9%
  - Negative factor: Tightening of insurance reimbursements by some insurance companies
  - Positive factor: Implementation of a strategy to promote switching from competing products
- ⇒ Flat sales volumes / Maintenance of unit prices
  Seikagaku export sales: +5.6%
- Increase due an inventory buildup by sales partner <<Other markets>> +13.3% (Seikagaku export sales) Continuing favorable local sales in China (+28%), higher shipments
- **FY2012 Full-year Forecasts +11.3% (year-on-year)** <<United States>> **+7.4%** (Seikagaku export sales)
- ♦ SUPARTZ<sup>®</sup>
- Local sales: At the previous year level due to sales expansion measures such as TV direct-to-consumer marketing
- Seikagaku export sales: Decrease due to carryover of shipments
- ♦ Gel-One<sup>®</sup>

Preparations for full-scale release underway following the winning patent lawsuit

#### ⇒Future new growth driver

- <<Other markets>> +21.2% (Seikagaku export sales)
- Favorable development of sales to China

Historical figures have been recalculated retrospectively to reflect the fact that milestone royalties were shifted from net sales to non-operating income from FY2010 onwards.



## Expanding Strategy of Gel-One<sup>®</sup> in the U.S.A.

## ■ Features of Gel-One<sup>®</sup> ≪High viscoelasticity≫



< Gel-One<sup>®</sup>, a single injection product for knee osteoarthritis pain> •Approval: March 2011 •Launch: January 2012

- A main ingredient is cross-linked hyaluronic acid using Seikagaku's proprietary technology.
- ⇒Highly viscoelastic properties to supplement synovial fluid.

#### ≪Effective in less volume≫

- Efficacy in a single 3mL injection
- $\Rightarrow$  contributes to alleviating patients' knee pain.

#### ≪Safety≫

 No statistically significant difference from placebo in rate of adverse events in the pivotal clinical trial.

## Sales Development of Zimmer, Inc.

- Zimmer is the market leader in the U.S. in replacement knee joints. It has excellent credibility and broad sales coverage in the orthopedic field.
- Implement proactive measures with Zimmer's orthopedic customers.
- Promote Gel-One<sup>®</sup>'s inclusion on formularies of private insurance companies and establish new sales routes.



Moving image of injection procedure

We aim to grow the viscosupplementation market and acquire market share by combining the unique features of Gel-One<sup>®</sup> with Zimmer's strong sales capabilities.

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## Sales of OPEGAN<sup>®</sup> (unit deliveries to medical institutions)

#### **OPEGAN®** deliveries to Medical Institutions

#### (Thousand units)



#### FY2012 1H Results (compared with FY2011/1H)

<<Market>>: +7.0%

-Market expansion due to an increase in the aged population -Rebound from the decrease in the number of operations in the previous 1H (impact of the earthquake and power outages) <<OPEGAN<sup>®</sup>>>: **+3.0%** 

-Despite an upturn in deliveries, lower market share attributable to intensified competition

⇒ Seikagaku sales down due in part to the impact of NHI drug price reductions

## **FY2012 Full-year Forecasts (year-on-year)** <<Market>>: +6.5%

-Gradual stabilization of the increase in reaction to the decrease in the number of operations in the previous fiscal year

⇒ Forecasted 6.1% increase in second half of the year <<OPEGAN<sup>®</sup>>>: +4.0%

- -Measures to commemorate the 25th anniversary of the launch of OPEGAN<sup>®</sup>, strengthening of information provision activities targeting medical institutions
- $\Rightarrow$  Aim for an increase in deliveries

Drug price revisions (effective April 2012)

- OPEGAN Hi<sup>®</sup>0.85: ¥7,714 (-9.7%)
- Industry average: -6.2%

OPEGAN<sup>®</sup> is an ophthalmic surgical aid with hyaluronic acid as Its main ingredient.

## **Basic Policy on Research and Development**



Point: Aiming for the rapid, continuous introduction of new products that meet high treatment needs, focusing on glycoscience as an area of specialization.

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Development code/ Product name, etc.	Lead indication	Target Market	Pre- clinical	ΡI	ΡI	PⅢ	Applic ation
SI-6603	Lumber Disk Herniation	Japan					
Condoliase <sup>*</sup>		U.S.					
SI-657	Enthesopathy	Japan					
Hyaluronic Acid	Additional indication for ARTZ	<b>P</b>					
SI-614	<b>D</b>						
Modified Hyaluronate	Dry eye	U.S.					
SI-615	Rheumatoid	lanan					
Adenosine A3 receptor agonist	Arthritis	Japan					
SI-613	Arthritic disorders						

Condoliase\*: generic name for Chondroitinase ABC

Substance: Condoliase

Indication: Lumber disc herniation

 Method of use: Injection into lumber disc (under X-ray observation)

#### [Current Stage]



Japan: PII

- Schedule

October 2011: Submission of a PIII clinical trial notification to the PMDA March 2012: Start of case registration Within FY2012: Case registration completed (estimate)

#### - Clinical Trial Summary

Examination of efficacy and safety in a randomized double-blinded comparative trial (against a placebo)

#### **United States: PII**

July 2012: Observation period completed

⇒ Under preparations for Phase III

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Substance: Hyaluronic acid (additional indication for ARTZ<sup>®</sup>)

Indication: Enthesopathy

\*Four conditions: Lateral epicondylitis, patellar tendinitis,

Achilles tendinitis, and plantar fasciitis

Development: Joint development with Kaken Pharmaceutical
 [Current Stage]

Japan: Pllb

-Schedule

Covers inflamed areas, penetrates tendons and ligaments, and provides pain relief

efficacy

An inflammatory condition that can occur due to undue burden where tendons and ligaments bond to bone

January 2012: Start of case registration for late Phase II clinical trial September 2012: Observation period completed ⇒now under the process of statistical analysis

#### Features:

- By covering and penetrating scars, degeneration or inflammatory reactions at tendon and ligament attachment sites, it is thought to exert an inhibitory action to suppress the symptoms of pain.
- Estimated number of patients : About 570,000 patients per year (total for four conditions)

- Substance : SI-614 (Modified Hyaluronate)
- Indication: Dry eye
- Formulation : Ophthalmic solution

[Current Stage]

#### **United States: PII**

- Schedule
  - March 2012: Start of case registration
  - July 2012: Observation period completed ⇒now under the process of statistical analysis

#### Features :

- SI-614 is a modified hyaluronate produced by Seikagaku's proprietary technology and it has an excellent tear film stabilizing effect.
- It is expected to improve the tear film instability of the three layers (lipid layer, aqueous layer, and mucin layer) and accompanied symptoms found in dry eye patients.
- •Estimated number of patients with moderate to severe: 4.9 million
- Although Dry eye is a multifactorial disease, only an anti-inflammatory drug is available in the U.S. currently. SI-614 will provide a new alternative to the treatment of dry eye through the promising mode of action.



#### **Ten-Year Vision and Mid-term Management Plan**

"Global Category Pharma" Converge major R&D resources on Glycoscience Establish Global Competitiveness

Build up a new market every 3 years, by launching a new product, and/or developing new regions

# ACT for the future 2018

<u>A</u>dvance: Highly advanced technologies <u>C</u>hallenge: Minds open to challenges <u>Transparency: A highly transparent company</u>



#### Cautionary statement regarding forward-looking information

This material includes forward-looking statements based on assumptions and beliefs in light of the information currently available to management and subject to significant risks and uncertainties. Actual financial results may differ materially depending on a number of factors including adverse economic conditions, currency exchange rate fluctuations, adverse legislative and regulatory developments, delays in new product launch, pricing and product initiatives of competitors, the inability of the company to market existing and new products effectively, interruptions in production, infringements of the company's intellectual property rights and the adverse outcome of material litigation. This material contains information on pharmaceuticals (including compounds under development), but this information is not intended to make any representations or advertisements regarding the efficacy or effectiveness of these preparations nor provide medical advice of any kind.





#### Mid-term Management Plan: Numerical Targets and Topics for Growth



#### Mid-term Management Plan: Trend in Capital Expenditures and Depreciation



such as for ARTZ Dispo® and Bulk products manufacturing facilities

# **Basic Policy on Profit Distribution**

### Dividends

Aim for stable and continuous dividends with a basis of an annual dividend of ¥25 per share.

#### Internal Reserve

Appropriated for R&D, and capital investment, etc., in accordance with medium-term focus

#### Flexible Capital Policy

Share buy-back is an option for improving capital efficiency

	FY2008	FY2009	FY2010	FY2011	FY2012 (Forecast)
Net Income per share	¥55.68	¥62.94	¥43.16	¥57.58	¥47.53
Annual Total Dividend	¥25.00	¥25.00	¥25.00	¥25.00	¥25.00
Dividend Payout Ratio	44.9%	39.7%	57.9%	43.4%	52.6%

## **Trend in Financial Index**

**50% Point:** In FY2011, the cost of sales ratio decreased due to decrease of depreciation of the No.4 Production Building. In FY2012, R&D expenses will increase attendant on progress with development themes.



## **Business Progress & Highlights**



## **Expanding Market of ARTZ® in Japan**

- Japanese knee osteoarthritis (OA) market continues to grow due to aging population
- There are 25 million latent patients with knee OA, whereas patients under treatment are 8 million (Survey conducted by the Tokyo University)



#### **Trend in NHI Reimbursement Price and Our Domestic Pharmaceuticals Sales**



## Measures Targeting Expansion of ARTZ<sup>®</sup> Sales

Improving the product value

⇒Responding to needs of medical fields by offering both plastic and glass syringes

#### **Glass Syringe**

# <image><text><text>

#### ≪Two types of a syringe≫



#### Plastic Syringe



#### **Sales Measures**

- ⇒ Approaches to medical institutions using brochures, etc. of disease awareness activities
- ⇒ Increased sales promotion efforts targeting medical specialists other than orthopedic surgeons

## **Trend in Hyaluronic Acid Products in Overseas Market**



## Sales of LAL Business (Value Basis)

#### Sales of LAL Business



## **FY2012 1H Results -17.2%(compared with FY11/1H)** <<Endotoxin-detecting reagents>>: -0.6%

- Japan: Firm sales of reagents for quality control to pharmaceutical companies and for hemodialysis quality management
- Overseas: Decrease on lower volumes of reagents for quality control and the impact of yen appreciation

\*Discontinuation of the research reagents business at the end of March 2012

- $\Rightarrow$  impact of approx. -¥350
- **FY2012 Full-year Forecasts -8.1% (year-on-year)** <<Endotoxin-detecting reagents>>: +2.8%
- Expected increase of reagents for quality control in Japan

and overseas, despite the impact of yen appreciation \*Discontinuation of the research reagents business at the end of March 2012

⇒ impact of approx. -¥450

#### Segment Changes

Business segments have been changed beginning in FY2012 due to the discontinuation of the research reagents business and the absorption-type merger of Seikagaku Biobusiness. Bulk Products will be included in the pharmaceuticals segment, and endotoxin-detecting reagents will be reported as the LAL segment.

#### Substance: Adenosine A3 receptor agonist

- Indication: Rheumatoid arthritis
- Formulation: Oral agent
- Origin: In-license from

Status:

Can-Fite BioPharma Ltd. Phase I in Japan



- Phase II in Europe, etc. implemented by Can-Fite
- $\Rightarrow$  Seikagaku will reassess its future development policy based on progress with the PIIb mono-therapy trial that is currently being implemented by the licensor, Can-Fite.

#### Features:

- In-license theme from Can-Fite BioPharma Ltd.
- Adenosine A3 receptor agonist selectively stimulates the adenosine A3 receptor, which is highly expressed in inflamed sites. It is thought to suppress cellular signal transduction, which contributes to inflammation, and the production of inflammatory cytokines.

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