Financial Results for the First Half of Fiscal Year 2014

(April 1, 2014 - September 30, 2014)





SEIKAGAKU CORPORATION

http://healthy-knee.com/

(TSE:4548)

Financial Results for 1H of Fiscal 2014

(Millions of Yen)

	FY2014 1H Results	FY2013 1H Results	vs. Previous Period	Initial Forecast for 1H (5/13)	vs. Initial Forecast for 1H
Net Sales	14,247	15,405	-1,157 (-7.5%)	14,150	+97 (+0.7%)
Operating Income	1,564	3,488	-1,923 (-55.1%)	1,450	+114 (+7.9%)
Ordinary Income	2,109	3,783	-1,673 (-44.2%)	1,750	+359 (+20.6%)
Net Income	1,687	3,118	-1,431 (-45.9%)	1,450	+237 (+16.4%)
R&D Expenses	3,397	3,068	+329 (+10.7%)	3,200	+197 (+6.2%)
R&D Expenses Ratio (to Net Sales)	23.8%	19.9%	+3.9pt	22.6%	+1.2pt
Net Income Per Share	¥29.71	¥54.90	-¥25.19	¥25.53	+¥4.18

Average Exchange Rate (1US\$) **EIKAGAKU CORPORATION** ¥103.05

¥98.86

¥102.00

Net Sales for 1H of FY2014 (year-on-year)

Net sales: ¥14,247 (-¥1,157, -7.5%)

(Millions of yen)

[Pharmaceuticals: ¥11,765 (-¥1,550)]

- Japan (-¥537)

ARTZ®, OPEGAN®: Seikagaku sales down due to the impact of NHI drug price reductions, despite higher volumes

MucoUp: Seikagaku sales show continued growth due to successful endoscopic surgery penetration

measures

- Overseas (-¥812)

ARTZ®: - U.S.; Seikagaku sales down sharply on the impact of an inventory build-up in 1H FY2013 and slight

lower local sales of SUPARTZ.

- China; Seikagaku sales at the prior-year level of due to inventory adjustments at the sales partner,

despite strong local sales of ARTZ

Gel-One[®]: Seikagaku sales at the prior-year level of due to shipment ahead of schedule in 1H FY2013,

despite a steady increase in local sales

- Bulk Products (-¥200) Decrease in sales of hyaluronic acid in an increasingly difficult market environment

[LAL: ¥2,482 (+¥392)] Higher sales of endotoxin-detecting reagents and the impact of yen depreciation

Decrease in sales due to NHI drug price reductions for domestic pharmaceuticals and lower shipments of overseas pharmaceuticals from high levels in 1H FY2013



^{*}Impact of yen depreciation on net sales: (+¥213)

Income for 1H of FY2014 (year-on-year)

(Millions of yen)

Operating Income: ¥1,564 (-¥1,923, -55.1%)

[Cost of Sales (+¥414)]

- *Cost of sales ratio: 41.3% (+5.8 pt)
- •Increase in depreciation accompanying the start of operation of new fixed assets and increase in the cost of sales ratio resulting from NHI drug price reductions

[SGA expenses (+¥352)]

•R&D expenses:\(\frac{\pmax}{3}\). Increase resulting from progress with development themes

Net Income: ¥1,687 (-¥1,431, -45.9%)

[Non-Operating Income/Expenses (+¥249)]

•Recording of a gain on the sale of investment securities (+¥262)

[Extraordinary Income/Loss (-¥49)]

- No extraordinary items recorded
 - *Reflects gain on the sale of investment securities and costs associated with integration of the Kurihama Plant, etc. in 1H FY2013.
- Decrease in income on lower sales coupled with higher depreciation accompanying the start of operation of new fixed assets and higher R&D expenses resulting from progress with development themes



Net Sales by Business Segment (1H of FY2014)

(Millions of Yen)

LAL Business: 17.4%(+3.8pt)

Net Sales ¥14,247 mil.

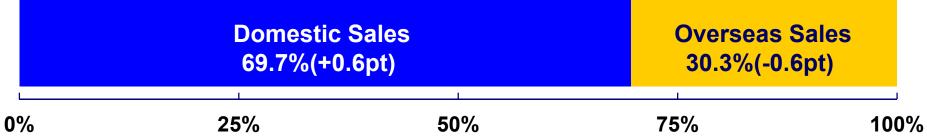
Pharmaceuticals: 82.6%(-3.8pt)

Domestic Pharmaceuticals: 60.8%

Overseas Pharmaceuticals: 17.2%

Bulk Products: 4.6%

Segment	Net Sales	vs. Previous Period	Change	
[Pharmaceuticals]	11,765	-1,550	-11.6%	
Domestic Pharmaceuticals	8,663	-537	-5.8%	
Overseas Pharmaceuticals	2,448	-812	-24.9%	
Bulk Products	652	-200	-23.5%	
[LAL Business]	2,482	+392	+18.8%	
Total	14,247	-1,157	-7.5%	
(Overseas Sales)	4,318	-445	-9.4%	





Results for 1H of FY2014 (comparison with the initial forecast)

(Millions of yen)

Net sales: ¥14,247 (+¥97, +0.7%)

- Pharmaceuticals (-¥84): Increase in sales for overseas pharmaceuticals and decrease for domestic pharmaceuticals and bulk products
- LAL (+¥182): Strong sales of the U.S. subsidiary

Operating income: ¥1,564 (+¥114, +7.9%)

SGA expenses (about -¥50): Increase in R&D expenses (+¥197; ¥3,200 → ¥3,397)
 as a result of progress with development themes being
 mostly offset by a decrease in other SGA expenses

Net income: ¥1,687 (+¥237, +16.4%)

- Increase in non-operating income:
 Increase in foreign exchange gains on foreign currency-denominated assets due to yen depreciation
 Decrease in facilities demolishing costs (loss on disposal of property, plant, and equipment)
 - Sales nearly in line with the initial forecast. Income higher than expected due to decrease SGA expenses and increase in foreign exchange gains on foreign currency-denominated assets due to yen depreciation



Overview of Forecast for FY2014

* There is no change in forecast announced on May 13, 2014.

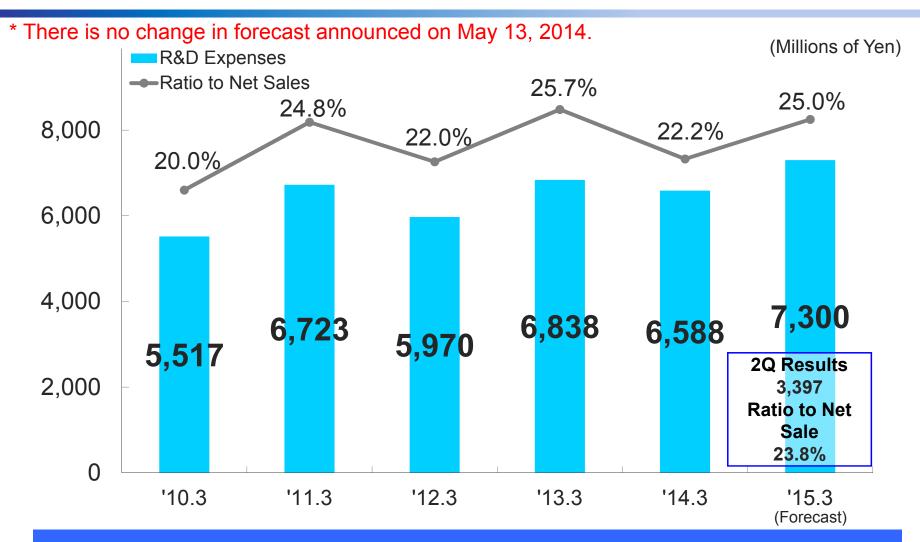
(Millions of Yen)

	FY2014 Forecast	FY2013 Results vs. Previous Year		(Reference) Degree of Progress	
Net Sales	29,150	29,614	-464 (-1.6%)	48.9%	
Operating Income	2,750	4,937	-2,187 (-44.3%)	56.9%	
Ordinary Income	4,200	5,878	-1,678 (-28.5%)	50.2%	
Net Income	3,450	4,745	-1,295 (-27.3%)	48.9%	
R&D Expenses	7,300	6,588	+711 (+10.8%)	46.5%	
R&D Expenses Ratio (to Net Sales)	25.0%	22.2%	+2.8pt	-	
Net Income Per Share	¥60.73	¥83.55	-¥22.82	-	

Average Exchange Rate (1US\$) ¥102.00 (Assumption)

¥100.24

Trend in R&D Expenses and Ratio to Net Sales



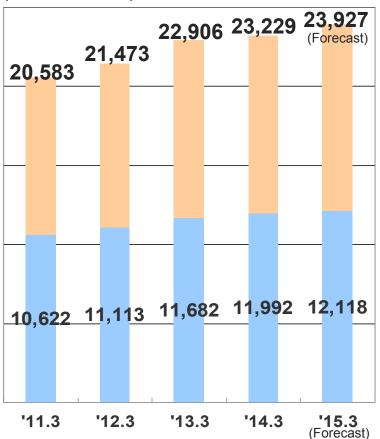
Increase in R&D expenses as a result of progress with SI-614 and other development themes, despite a decrease for SI-6603 in Japan after it reached the NDA stage



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

ARTZ® Deliveries to Medical Institutions

(Thousand Units)



- Units delivered to medical institutions (full year)
- Units delivered to medical institutions (1H)

SEIKAGAKU CORPORATION

FY2014 1H Results (year-on-year)

≪Market≫: -0.8%

≪ARTZ[®]≫: +1.1%

- Negative market growth due to multiple factors
- Market share increase for ARTZ resulting from sales expansion efforts

⇒Market share: 57.8% (+1.1 pt)

FY2014 Forecast (year-on-year)

≪ARTZ®≫: +3.0%

- Implementation of disease awareness activities in selected key areas
- Also focus on departments other than orthopedic surgery and hospitals that do not yet use ARTZ
- ⇒Aim for market share of 58.0% (+1.5 pt).

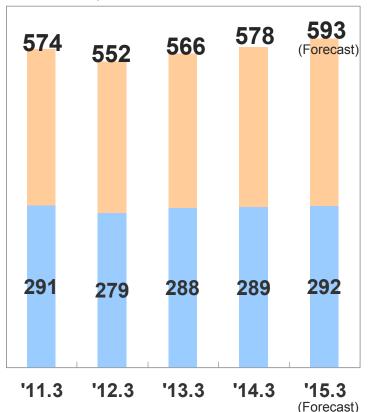
Drug price revision ('14/4~; excluding consumption tax hike)
•ARTZ Dispo®:¥1,453(-7.4%) •Industry average:-5.7%

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

Sales of OPEGAN® (unit deliveries to medical institutions)

OPEGAN® deliveries to Medical Institutions

(Thousand units)



- Units delivered to medical institutions (full year)
- Units delivered to medical institutions (1H)

FY2014 1H Results (year-on-year)

<<Market>>: +2.2%

 Market expansion in line with increase in the aged population

<<OPEGAN®>> : +1.1%

 Decrease in market share amid continuing intense competition

⇒Market share: 34.8% (-0.3 pt)

FY2014 Forecast (year-on-year)

<<OPEGAN®>> : **+2.5**%

- Implementation of product improvements and measures to strengthen information provision activities
 - + Pursuit of long-term share recovery through product mix enhancement.

Drug price revision ('14/4~; excluding consumption tax hike)

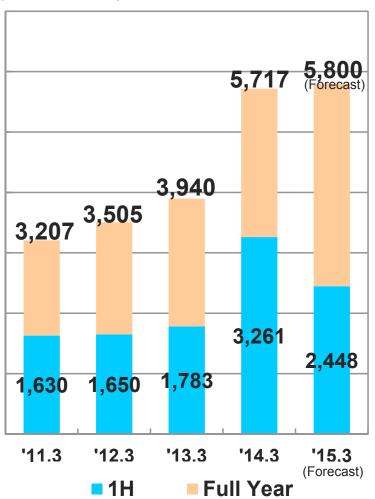
•Opegan Hi® 0.85:¥7,090(-10.6%) •Industry average: -5.7%

OPEGAN® is an ophthalmic surgical aid with hyaluronic acid as its main ingredient.

Overseas Pharmaceuticals (value basis/ year-on-year)

Overseas Pharmaceuticals Sales

(Millions of Yen)



FY2014 1H Results: ¥2,448 million (-24.9%)

- ≪ARTZ (multiple injection)≫ -32.3% (Seikagaku export sales)
- ◆SUPARTZ in the U.S.: Slightly decrease due to growth from competing 3-5 injection products
- •ARTZ in China: Continued growth due to reputation for high quality
- Seikagaku export sales: Decrease following an inventory build-up of SUPARTZ by sales partner in FY2013
- ≪Gel-One (single injection)≫ -0.1% (Seikagaku export sales)
- Strong local sales, but Seikagaku sales at the prior-year level due to shipment ahead of schedule FY2013

FY2014 Forecast: **¥**5,800 million (+1.4%)

*No change from the forecast announced on May 13, 2014

- ≪ARTZ ≫ -11.4% (Seikagaku export sales)
- ◆SUPARTZ in the U.S.: Continued intense competition ⇒As a countermeasure, conducted a labeling change clinical trial (from 5 → 3 injections)
- •ARTZ in China: Expected double-digit growth in local sales
- Seikagaku export sales: Sales decrease following the SUPARTZ inventory build-up
- ≪Gel-One ≫ +52.7% (Seikagaku export sales)
- Expected 2H increase in shipments accompanying higher local sales



Future Gel-One® Initiatives

≪Sales Partner (Zimmer) Initiatives≫

- Measures to increase products awareness through sales structure reinforcement
- Further cultivation of existing sales channels
 - Inclusion on private insurance (medical benefits) formularies are a key task.
 - Sales promotion reinforcement in channels with potential for reimbursement (private insurance (drug benefits)/public insurance)



Single-injection joint function improving agent Gel-One®

≪Seikagaku Initiatives≫

- Product value enhancement measure (labeling change clinical trial)
 - Extension of effectiveness (13 weeks→26 weeks), safety of retreatment
- Opening of the SEIKAGAKU U.S.A. Representative Office

Steady market penetration and acquisition of share from competitors



Opening of the SEIKAGAKU U.S.A. Representative Office





Single-injection product Gel-One®



Multiple-injection product SUPARTZ®

SEIKAGAKU U.S.A. Representative Office



Jersey City, NJ



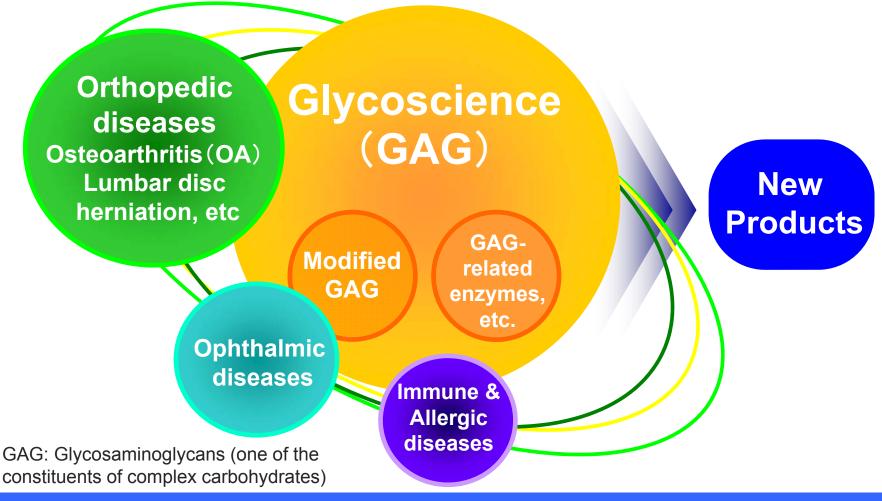
- ◆ Overview of the Representative Office ◆
- Date of opening: October 15, 2014 (local time)
- Purpose: Provision of product education to local sales reps, gathering of information on the U.S. market



KAGAKU CORPORATION

Further acceleration of sales of Gel-One[®] and SUPARTZ[®] through reinforcement of support for sales activities

Basic Policy on Research and Development



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



Pipeline List

Development code/ Product name, etc.	Lead indication	Target Market	PΙ	PΙ	РШ	Appli- cation
SI-6603	Lumber Disk	Japan				
Condoliase	Herniation					
SI-657 Hyaluronic Acid	Enthesopathy Additional indication for ARTZ	Japan				
SI-614 Modified Hyaluronate	Dry eye	U.S.			PI	/Ш
SI-613 Hyaluronic Acid-NSAID conjugates	Knee Osteoarthritis	Japan				
SI-615 Adenosine A3 receptor agonist	Rheumatoid Arthritis	Japan				



SI-6603 Outline

Reduces nerve pressure and alleviates pain by shrinking herniation

NDA submitted in Japan in January 2014

■ Planned start of an open-label trial in February 2015

Substance: Condoliase

Indication: Lumbar disc herniation

Method of use: Injection into lumbar disc

(under X-ray observation)

Current stage:

Japan: Filed

♦ NDA submitted in January 2014

◆ Academic conference presentation in June 2014

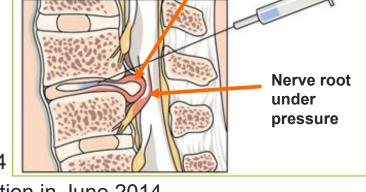
(41st Annual Meeting of International Society for the Study of the Lumbar Spine)

U.S.: PIII

- Case registration started in October 2013
- Planned start of an open-label trial for the purpose of safety evaluation in February 2015

Features:

- Pain alleviated by reducing hernia-related nerve pressure through the specific degradation of GAGs (chondroitin sulfate, etc.), which are the main components of the nucleus pulposus
- No breakdown of proteins, so no effect on other tissues (blood vessels, nerves, etc.)
- Single-injection treatment with SI-6603 expected to become an alternative to surgery
- Seikagaku concluded an exclusive distributorship agreement in Japan with Kaken Pharmaceutical Co., Ltd.



Extruded pulposus (hernia)

SI-657 Outline

- Exerts an inhibitory action to improve symptoms of enthesopathy
- Case registration for a Phase III clinical trial completed in October 2014
- **Substance**: Hyaluronic acid (additional indication for ARTZ®)
- Indication: Enthesopathy (targets; four conditions)
- Development: Joint development with Kaken Pharmaceutical



 Lateral epicondylitis (tennis elbow)



Achilles tendinitisplantar fasciitis



 patellar tendinitis (jumper's knee)

Estimated annual number of patients (total for four conditions): About 570,000

The aim is to contribute to symptom improvement in more patients by further increasing the added value of ARTZ.

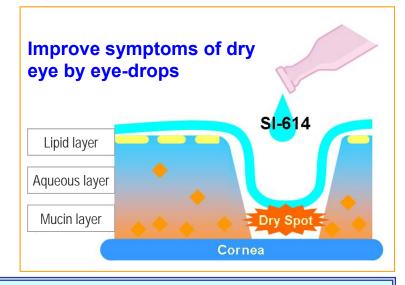
SI-614 Outline

- Improves symptoms of dry eye by protecting the ocular surface and promoting corneal epithelial wound healing
- Case registration for a Phase II / III clinical trial completed in October 2014
- **Substance**: SI-614 (Modified Hyaluronate)
- Indication: Dry eye
- Formulation: Ophthalmic solution
- Current Stage : U.S. : PII / III
 - ♦ May 2014:

Phase II / III clinical trial started

◆ October 2014:

Case registration completed



Features:

- SI-614 is a modified hyaluronate produced by Seikagaku's proprietary technology.
- It is expected to improve symptoms of dry eye by protecting the ocular surface and promoting corneal epithelial wound healing in dry eye patients.
- 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.

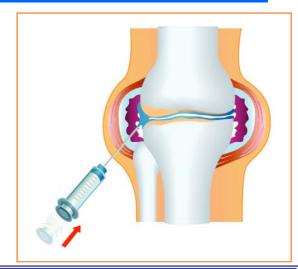


SI-613 Outline

- Prompt and long-term relief of severe pain and inflammation associated with knee osteoarthritis
- Planned start of a Phase II clinical trial multiple dose study in December 2014
- Substance: SI-613

(Hyaluronic acid-NSAID*1 conjugates)

- Indication: Knee Osteoarthritis
- **Formulation:** Injection into knee joint
- Current stage: Japan: PII
 - October 2014: Submission of notification of a Phase II trial (multiple dose study)
 - ◆December 2014: Planned start of case registration



Features:

- Hyaluronic acid combined with NSAID for relief of severe pain and inflammation of OA using Seikagaku's unique technology
- Sustained-release*2 of the NSAID for long-term improvement of severe pain and inflammation
- Minimal side effects compared to oral or topical treatment of the NSAID

^{*2} Sustained release: Gradual release of active ingredients to produce a sustained therapeutic effect over a long period



^{*1} NSAID: Non-Steroidial Anti-Inflammatory Drug

Basic Policy on Profit Distribution

* There is no change in forecast announced on May 13, 2014.

Dividends

Aim for stable and continuous dividends with a basis of an annual dividend of ¥26 per share.

Internal Reserve

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

♦ Flexible Capital Policy

Share buy-back is an option for improving capital efficiency

	FY2010	FY2011	FY2012	FY2013	FY2014 (Forecast)
Net Income per share	¥43.16	¥57.58	¥57.33	¥83.55	¥60.73
Annual Total Dividend	¥25.00	¥25.00	¥25.00	¥26.00	¥26.00
Dividend Payout Ratio	57.9%	43.4%	43.6%	31.1%	42.8%

Exploring the Innovative Promise of Glycoscience

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.



Appendix



Ten-Year Vision and Mid-term Management Plan

Ten-Year Vision "Global Category Pharma"

Converge major R&D resources on Glycoscience and establish global competitiveness

ACT for the future

Advance · Challenge · Transparency

Cultivation of new leads for Achieving the Ten-Year Vision

Fostering of basic corporate strength and development of core systems

Step 1

FY2009 ~ 2011

Step 2

FY2012 ~ 2015

Vision realization

Step 3

FY2016 ~ 2018



Trend in Capital Investments

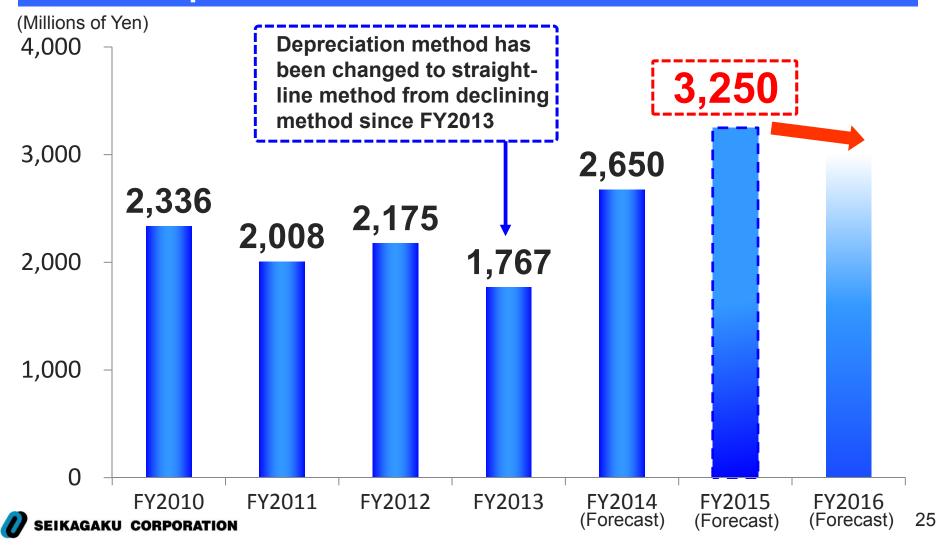
Facilities	Amounts (¥ bill.)	FY2010	FY2011	FY2012	FY2013	FY2014 (Forecast)	FY2015 (Forecast)
SI-6603 Bulk Production Facilities	1.1					Start '14.10	
No. 5 Production Building (for ARTZ Dispo®)	9.8		Start '12.3				Operation (plan) '15.1
Hyaluronic Acid Bulk Production Facilities	3.1		Start '12.1			Operation '14.2	
Facilities for Gel-One®	3.0		Start '11.12			peration 13.10	
Chondroitin Sulfate Bulk Production Facilities	1.2	Star '11.		Operat '12.			
Amounts (Millions of)		1,306	5,718	9,164	7,222	2,500	-



Trend in Depreciation

* There is no change in forecast announced on May 13, 2014.

Depreciation will peak with ¥3,250 million at FY2015 by active capital investments



Forecasts for FY2014 (Year-on-Year)

* There is no change in forecast announced on May 13, 2014.

(Millions of Yen)

Net sales: ¥29,150 (-¥464, -1.6%)

- Domestic pharmaceuticals (about -¥700): Higher volumes fail to compensate for NHI drug price reductions
- Overseas pharmaceuticals (about +¥100): Increase for Gel-One and sales to China compensate for a decrease in SUPARTZ following an inventory build-up in FY2013
- LAL (approx. +¥300): Increase in sales at the U.S. subsidiary
 *Impact of yen depreciation on overall net sales (approx. +¥250)

Operating income: ¥2,750 (-¥2,187, -44.3%)

*Higher depreciation accompanying the start of operation of new facilities ($\pm 1,767 \Rightarrow \pm 2,650$)

- Cost of sales (about +¥600): Higher depreciation accompanying the start of operation of new facilities
- SG&A expenses (about +¥1,100): R&D expenses: +¥711 (progress of SI-657, SI-614 and other development themes)

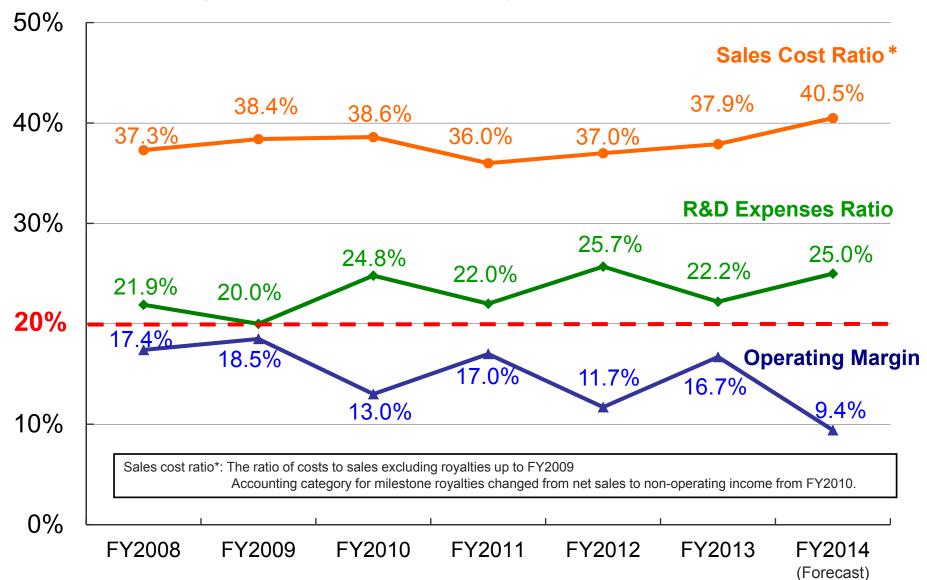
Increase in sales-related expenses for Gel-One and other products

Net income: ¥3,450 (-¥1,295, -27.3%)

- Increase in non-operating income(approx. +¥600): Increase in royalty income
- Decrease in corporate tax rate: early termination of the special corporate tax for reconstruction (tax increase)
- Lower sales and income due to NHI drug price reductions, higher depreciation accompanying the start of operation of new facilities, and SG&A expenses such as R&D expenses due to progress with development themes

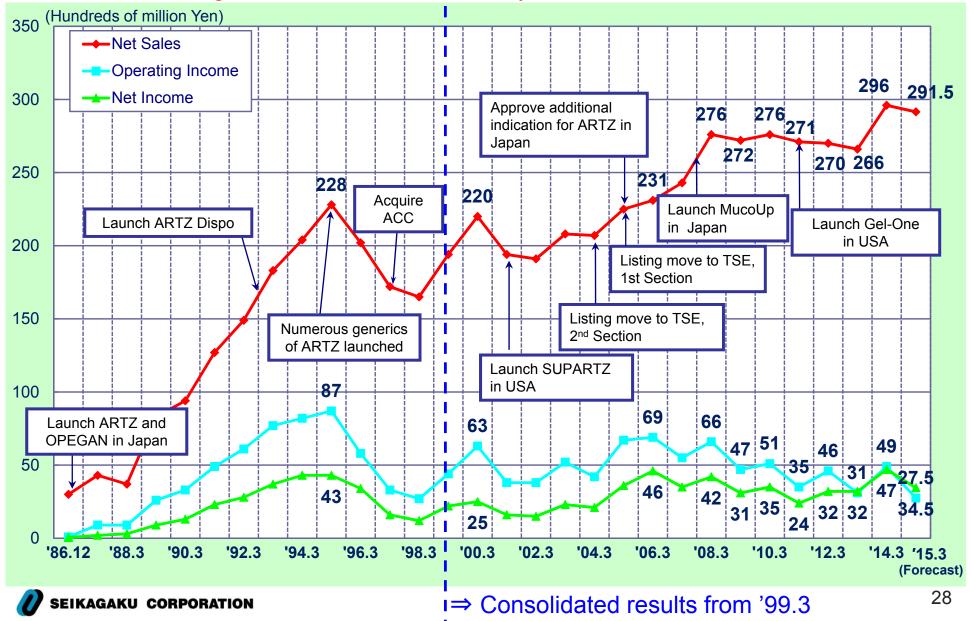


Trend in Financial Index

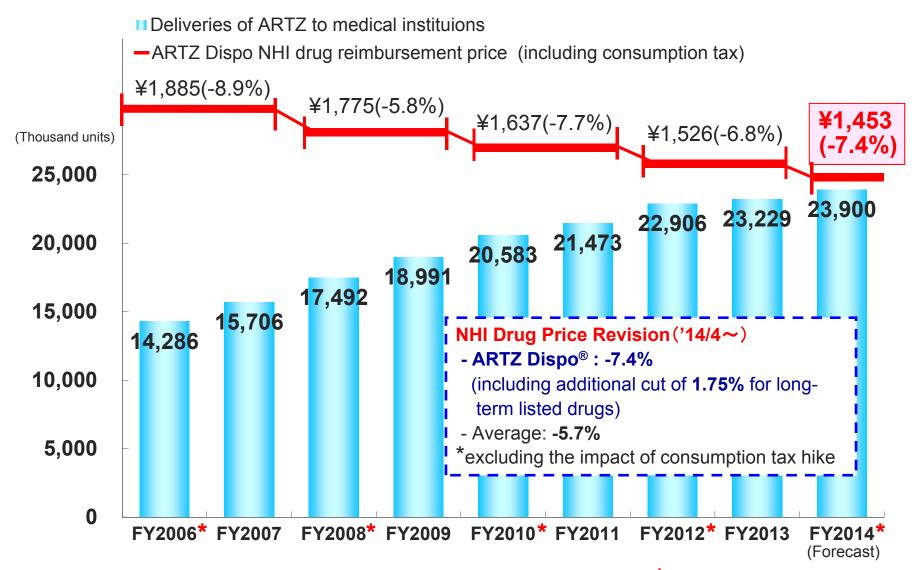




Business Progress & Highlights



Trend in NHI Reimbursement Price and Our Domestic Pharmaceuticals Sales

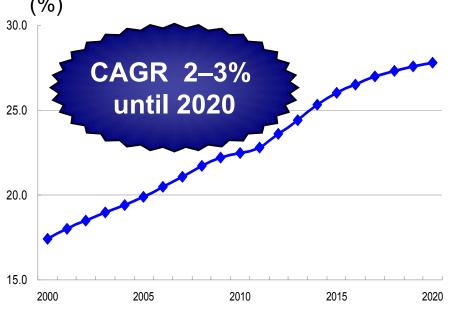


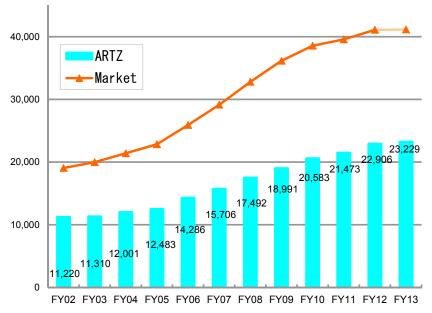


Market Environment for ARTZ® in Japan

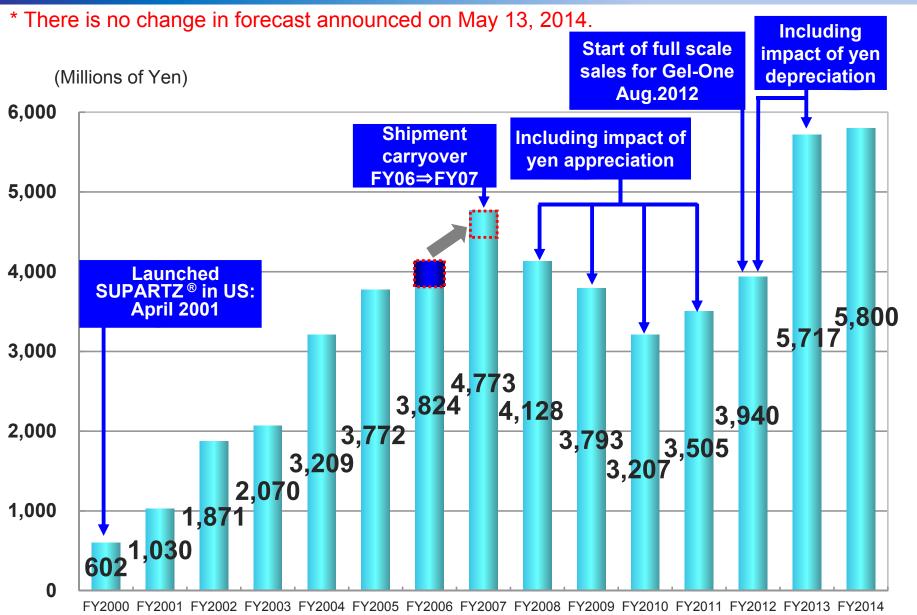
- •The Japanese aged population is growing by 2-3% per year until 2020.
- There are 25 million latent patients with knee OA, whereas patients under treatment are 8 million (Survey conducted by the Tokyo University)

Growing Elderly Population (65 or over)
(Source: Ministry of Internal Affairs and Communications)
(%)
(Thousand units)



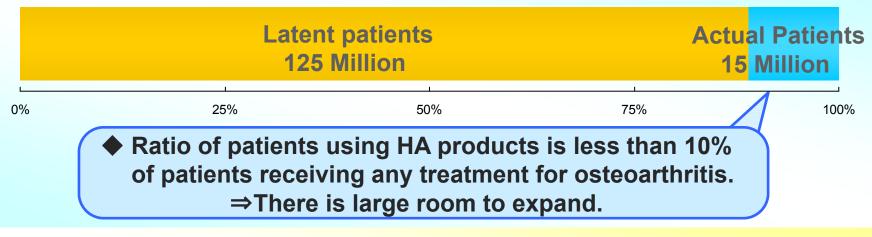


Trend in Overseas Sales of Hyaluronic Acid Products



U.S. Market for HA Products

■ Number of osteoarthritis patients (estimate)





2013
3-Injection US\$ 840 Mil.
45%

5-Injection 15%

Single Injection 40%

♦Outlook: continued market growth of 6% to 7% per year

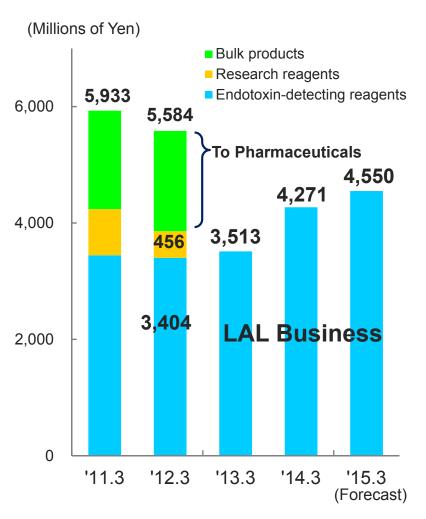
* Numbers in this slide are estimated by Seikagaku



Sales of LAL Business (Value Basis)

* There is no change in forecast announced on May 13, 2014.

Sales of LAL Business



FY2014 1H Results: +18.8%(year-on-year)

Japan: Increases in reagents for quality control and related equipment

Overseas: Sales of ACC, a U.S. subsidiary ACC, increased due to impact of yen depreciation and an increase in endotoxin reagents

FY2014 Forecasts: +6.5%(year-on-year)

Japan: Slight increase due to an increase in reagents for quality control

Overseas: ACC sales increase mainly due to yen depreciation

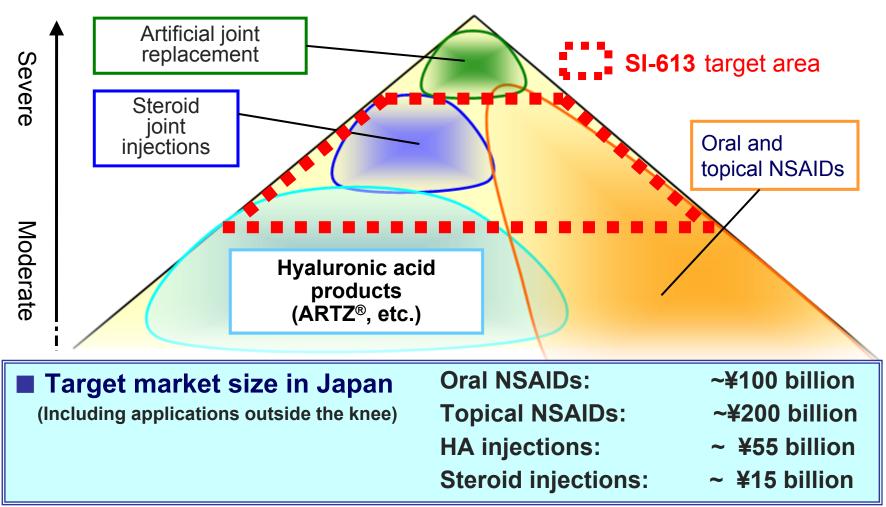
Segment Changes

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 endotoxindetecting reagents will be reported as the LAL segment.



SI-613 Target Patients

Patients with severe pain and being treated with oral or topical NSAIDs or intra-articular steroid injection





SI-615 Outline

- Oral agent for rheumatoid arthritis in-licensed from CanFite
- Reassessing future development policy based on progress with PIIb trial by the licensor

Substance: Adenosine A3 receptor agonist

Indication: Rheumatoid arthritis

Formulation: Oral agent

Current stage:

Japan: Pl

Phase I single administration clinical trial completed in May 2009

Europe: Pllb

Implemented by Can-Fite

⇒ Seikagaku will reassess its future development policy based on results from the PIIb mono-therapy 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.

Special Profile

1_{st}

Specialization in glycoscience

- Niche field, market not big enough for the major pharmaceutical companies to penetrate
- Focusing on this field more than 60 years

2_{nd}

Unique business model

- Concentration on R&D and manufacturing
- R&D staff comprising **one-third** of our total employees
- Allocation of over 20% of net sales to R&D investment

3rd

High-level extraction & purification technologies

ARTZ® (main product) has been administered in more than 330 million injections without major side effects over more than 25 years



Our Business Segment

Pharmaceutical Business Domestic

Overseas

⇒19.3%

Pharmaceuticals

Domestic
Pharmaceuticals
⇒60.8%

Joint Function Improving Agents







85.6%

Net Sales

¥29,614million

(FY2013 Results)

Ophthalmic Surgical Aids



Surgical Aids for Endoscopic Mucosal Resection



Bulk Products ⇒5.5%

Bulk Products











Endotoxin-detecting reagents (used mainly for quality control of pharmaceuticals and medical devices) 37



Main Hyaluronic Acid (HA) Products

- ARTZ® Knee osteoarthritis (OA) pain relief by multiple injections
- ◆ The first HA joint function improving agent in the world
- Main distributors:

Kaken Pharmaceutical (Japan): ARTZ®

Bioventus (U.S.): SUPARTZ®

Kunming Baker Norton Pharmaceutical (China): ARTZ®



- Gel-One® Knee OA pain relief by a single injection
- Victory in the patent lawsuit confirmed (January 2014)
- ◆ Distributor: Zimmer (U.S.)



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