### Financial Results for the Fiscal Year 2013 (April 1, 2013 – March 31, 2014)

**Exploring the Innovative Promise of Glycoscience** 



http://healthy-knee.com/



(TSE:4548)

## **Financial Results for FY2013**

(Millions of Yen)

					<b>`</b>
	FY2013 Results	FY2012 Results	vs. Previous Year	Forecast Nov.6,2013 Announcement	vs. Forecast
Net Sales	29,614	26,639	<b>+2,975</b> (+11.2%)	30,200	<b>-585</b> (-1.9%)
Operating Income	4,937	3,126	<b>+1,811</b> (+57.9%)	4,800	<b>+137</b> (+2.9%)
Ordinary Income	5,878	4,302	<b>+1,575</b> (+36.6%)	5,500	<b>+378</b> (+6.9%)
Net Income	4,745	3,256	<b>+1,489</b> (+45.7%)	4,450	<b>+295</b> (+6.7%)
R&D Expenses	6,588	6,838	<b>-249</b> (-3.7%)	6,900	<b>-311</b> (-4.5%)
R&D Expenses Ratio (to Net Sales )	22.2%	25.7%	-3.5pt	22.8%	<b>-0.6</b> p
Net Income Per Share	¥83.55	57.33円	+¥26.22	¥78.34	+¥5.21
Average Exchange Rate (1US\$) SEIKAGAKU CORPORATI	+100.24	¥83.11	¥97.00 (2 <sup>nd</sup> half assumption)		

## Net Sales in FY2013 (Year-on-Year)

### Net sales: ¥29,614 (+¥2,975, +11.2%)

(Millions of Yen)

### [Pharmaceuticals: ¥25,342 (+¥2,217)]

#### - Japan (+¥228)

ARTZ<sup>®</sup>: Seikagaku sales and share up, but a lower growth rate in a soft market
 OPEGAN<sup>®</sup>: Seikagaku sales up, but intense competition leads to a share decrease
 MucoUp<sup>®</sup>: Seikagaku sales up due to successful measures to penetrate endoscopic surgery

#### - Overseas (+¥1,766)

ARTZ<sup>®</sup>: -U.S.; Lower local sales of SUPARTZ. Seikagaku sales up thanks to the impact of yen depreciation and an inventory build-up by the sales partner
 -China; Impact of bribery allegations involving unrelated foreign-based pharmaceutical companies have nearly run their course. Seikagaku sales up

Gel-One<sup>®</sup>: Seikagaku sales up, but a lower than expected growth rate because sales infrastructure development is taking time

- Bulk Products (+¥212): ): Increase in sales of hyaluronic acid

[LAL: ¥4,271 (+¥757)] Increase in overseas sales and the impact of yen depreciation

\*Impact of yen depreciation on net sales: (about +¥1,540)

# Increase in sales due to higher volumes of Gel-One and the impact of yen depreciation

## Income in FY2013 (Year-on-Year)

### **Operating Income: ¥4,937 (+¥1,811, +57.9%)**

(Millions of Yen)

\*Impact on income of change in depreciation method (declining-balance method ⇒ straight-line method): (about + ¥590)

#### [Cost of Sales (+¥1,356)]

\*Cost of sales ratio: 37.9% (+0.9pt.)

- Increase in the cost of sales ratio resulting from higher test run costs of new production facilities, despite higher volumes of overseas pharmaceuticals and the impact of yen depreciation

#### [SGA expenses (-¥192)]

R&D expenses: ¥6,588 (-¥249): Decrease in depreciation and other indirect costs

- Decrease in Gel-One lawsuit expenses

#### <u>Net Income: ¥4,745 (+¥1,489, +45.7%)</u> [Non-Operating Income/Expenses (-¥235)]

- Increase in royalty income (-¥523)

- Impact of yen depreciation on valuation of foreign currency-denominated assets (+¥235)

### [Extraordinary losses (+¥71)]

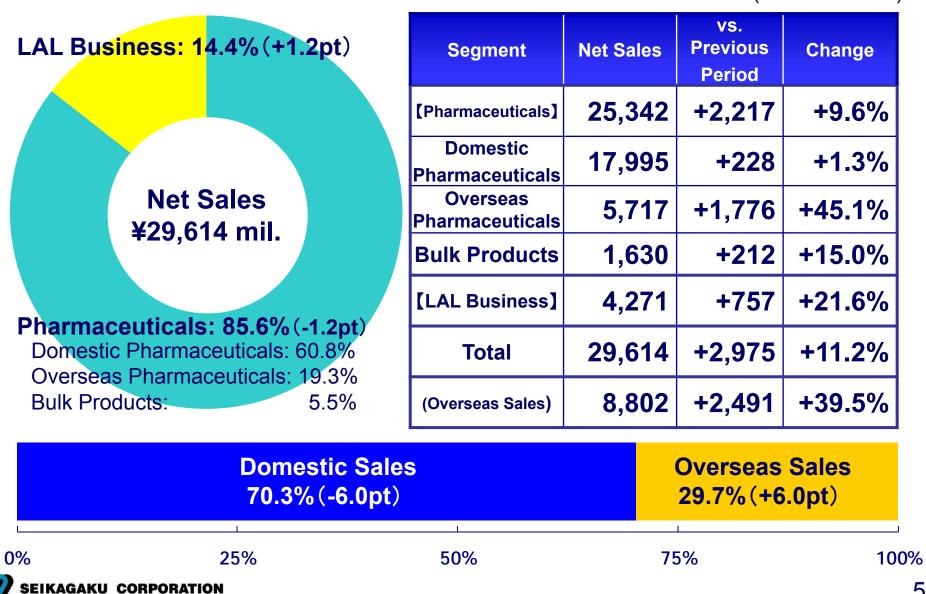
- Recording of an extraordinary gain on the sale of investment securities (+¥596)
- Recording of an extraordinary loss on costs associated with integration of the Kurihama Plant, etc. (-¥524)

\*Decrease in tax expense from continuous application of preferential taxation due to designation of the Takahagi Plant as a special district for industrial revitalization (24.3%  $\Rightarrow$  20.2%)

Sharp increase in income due to higher gross profit, lower R&D expenses and other SGA expenses

## **Net Sales by Business Segment**

(Millions of Yen)



### Comparison with Forecasts for FY 2013 (announced on Nov. 6, 2013)

(Millions of Yen)

### Net sales: ¥29,614 (-¥585, -1.9%)

 Pharmaceuticals (-¥707): Lower sales volumes of domestic and overseas pharmaceuticals, despite the impact of yen depreciation

• LAL (+¥121): Increase in sales at an overseas subsidiary

### **Operating income: ¥4,937 (+¥137, +2.9%)**

 SGA expenses (approx. -¥650): R&D expenses (-¥311) Forecast ¥6,900 ⇒ Actual: ¥6,588 Sales-related expenses: Decrease accompanying lower pharmaceuticals sales

### Net income: ¥4,745 (+¥295, +6.7%)

- Increase in non-operating income: Increase in foreign exchange gains related to valuation of foreign currency-denominated assets, reflecting the impact of yen depreciation
  - Lower sales on decreased sales volumes of domestic and overseas pharmaceuticals
  - Higher income due to lower SGA expenses and an increase
    - in non-operating income

# **Overview of Forecast for FY2014**

(Millions of Yen)

	FY2014 Forecast	FY2013 Results	vs. Previous Year
Net Sales	29,150	29,614	<b>-464</b> (-1.6%)
Operating Income	2,750	4,937	<b>-2,187</b> (-44.3%)
Ordinary Income	4,200	5,878	<b>-1,678</b> (-28.5%)
Net Income	3,450	4,745	<b>-1,295</b> (-27.3%)
R&D Expenses	7,300	6,588	<b>+711</b> (+10.8%)
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	



## Forecasts for FY2014 (Year-on-Year)

### Net sales: ¥29,150 (-¥464, -1.6%)

(Millions of Yen)

- 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
- SGA expenses (about +¥1,100): R&D expenses: +¥711 (progress of SI-657, SI-614 and other

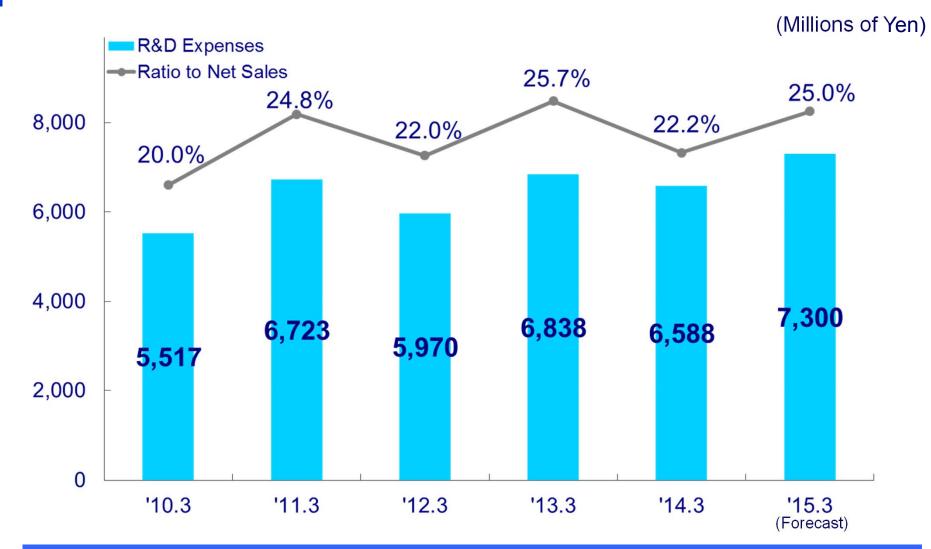
development themes) Increase in sales-related expenses for Gel-One and other products

### 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 SGA expenses such as R&D expenses due to progress with development themes

### **Trend in R&D Expenses and Ratio to Net Sales**



R&D expenses for FY2014 of ¥7,300 million due to progress of development themes such as SI-657, SI-614, and SI-6603 in the U.S.

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

#### FY2013 Results (year-on-year)

**ARTZ® Deliveries to Medical Institutions** 

#### (Thousands units)



</br>

- <<ARTZ<sup>®</sup>>>: +1.4%
- Slowing of the market growth rate due to complex factors
- Increase in market share for ARTZ as a result sales expansion efforts
  - ⇒Market share: **56.5%(+0.8pt**)

#### FY2014 Forecasts (year-on-year)

- <<ARTZ<sup>®</sup>>>: +3.0%
- Continuing implementation of disease awareness activities
- Appealing the unique medicinal action of hyaluronic acid (chondroprotection, etc.)
- Meeting medical needs by offering both plastic and glass syringes
- Expanding focus beyond orthopedic surgery to other departments and institutions not using ARTZ

#### ⇒Market share: Aim for 58.0%(+1.5pt)

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

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

#### SEIKAGAKU CORPORATION

### $\label{eq:sales} Sales of OPEGAN^{\textcircled{R}} \ (unit \ deliveries \ to \ medical \ institutions)$

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

#### (Thousand units)



#### FY2013 Results (year-on-year)

<<Market>>: +5.0%

- Expansion resulting from an increase in the aged population
- Temporary demand due to NHI drug price revision (change in rules governing generics)

<<OPEGAN®>>:+2.1%

Decrease in market share amid continuing intense competition

#### FY2014 Forecasts (year-on-year)

<<OPEGAN®>>: +2.5%

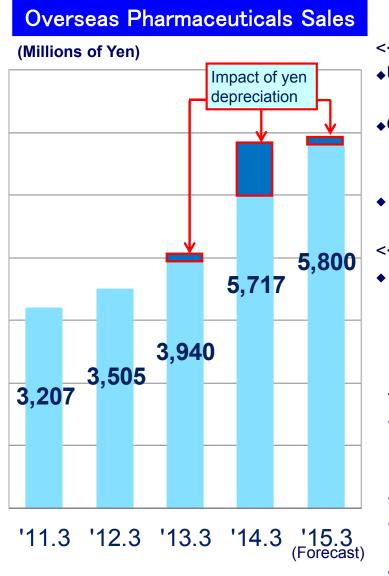
- Implementation of product improvements and measures to strengthen information provision activities
- ⇒ Forecast of growth in line with the rate of increase in the aged population

### + Pursuit of long-term share recovery through product mix enhancement.

Drug price revision ('14/4~; excluding consumption tax hike) •Opegan Hi<sup>®</sup> 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)



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(Impact of ven depreciation: about +¥100 million) <<ARTZ<sup>®</sup> (multiple injection)>>: -11.4% (Seikagaku export sales)

- U.S.: Continued intense competition
  - $\Rightarrow$  As a countermeasure, start of a labeling change clinical trial (from  $5 \rightarrow 3$  injections)
- China: Expected double-digit growth in local sales
- Seikagaku export sales: Sales decrease following the SUPARTZ inventory build-up in FY2013
- <<Gel-One<sup>®</sup> (single injection)>> +52.7% (Seikagaku export sales)
- Acceleration of sales infrastructure development

#### FY2013 Results: ¥5,717 million (+45.1%)

(Impact of yen depreciation: about +¥900 million)

<<ARTZ<sup>®</sup> (multiple injection)>>: +24.7% (Seikagaku export sales)

- •U.S: Decrease in local sales due to higher sales of competing 3-injection products (-3.0%)
- China: Impact of bribery allegations involving unrelated foreignbased pharmaceutical companies have nearly run their course. Local sales up (+15%)
- Seikagaku export sales: Increase due to an inventory build-up of SUPARTZ in the U.S. in addition to yen depreciation
- << Gel-One<sup>®</sup> (single injection)>>
- A sharp increase in both local sales and Seikagaku export sales, but a lower than expected rate of growth

#### FY2014 Forecasts: ¥5,800 million (+1.4%)

### **Gel-One Challenges and Strategic Initiatives**

# Local sales infrastructure development is an urgent priority.

Product Awareness Raising

 Reinforcement of the sales infrastructure
 ⇒ Further cultivation of existing sales channels



Gel-One<sup>®</sup> Cross-linked Hyaluronate 3 mL Complete Treatment

Further Sales Channel Expansion

 Continued negotiation with private insurance companies by a dedicated negotiating team

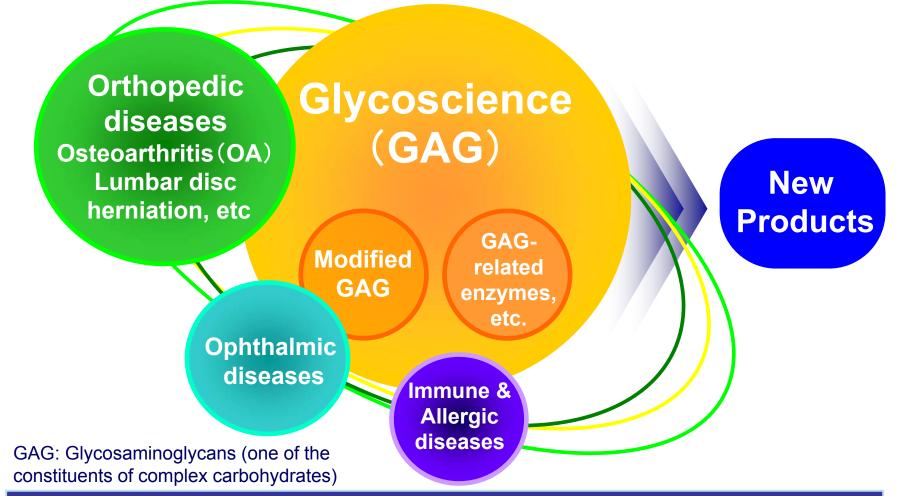
Measures to increase Gel-One's product strengths and enhance product value

- Single injection of a low-volume (3 ml) dose / Safety demonstrated in clinical trials
- •a labeling change (addition) clinical trial ongoing (August 2013)

Proceed with exploration of the market for a single-injection product through product awareness-raising and further sales channel expansion.



### **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.

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# **Pipeline List**

Development code/ Product name, etc.	Lead indication	Target Market	ΡI	ΡI	PⅢ	Appli- cation
SI-6603	Lumber Disk	Japan			ʻfile	<b>d</b> in '14.1
Condoliase	Herniation	U.S.				
SI-657 Hyaluronic Acid	Enthesopathy Additional indication for ARTZ	Japan				
SI-614 Modified Hyaluronate	Dry eye	U.S.		IND si	P II	
SI-613 Hyaluronic Acid-NSAID conjugates	Knee Osteoarthritis	Japan				
SI-615 Adenosine A3 receptor agonist	Rheumatoid Arthritis	Japan				

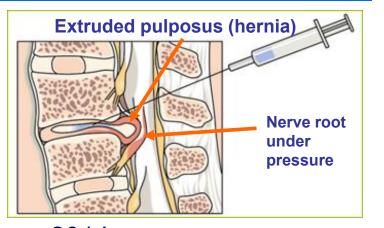


## SI-6603 Outline

Reduces nerve pressure and alleviates pain by shrinking herniation NDA submitted in Japan in January 2014

Substance:CondoliaseIndication:Lumbar disc herniationMethod of use:Injection into lumbar disc<br/>(under X-ray observation)

#### Current stage:



Japan: Filed NDA submitted in January 2014

Academic conference presentation planned 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

#### 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.

## SI-657 Outline

- Exerts an inhibitory action to improve symptoms of enthesopathy Japan Phase III trial started in May 2013 making steady progress
- **Substance:** Hyaluronic acid (additional indication for ARTZ<sup>®</sup>)
- Indication: Enthesopathy (targets; four conditions)
- **Development:** Joint development with Kaken Pharmaceutical
- Current stage: Japan:PIII





 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
 IND for Phase II/III clinical trial submitted to FDA in May 2014

Substance: SI-614 (Modified Hyaluronate)

Indication: Dry eye

Formulation: Ophthalmic solution

Current Stage : United States: PII/III

September 2012: Completion of Phase II clinical trial

♦ May 2014:

Phase II/III clinical trial started

### Improve symptoms of dry eye by eye-drops Lipid layer Aqueous layer Mucin layer

#### 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 Global development including the U.S. and other areas

Substance: SI-613

(Hyaluronic acid-NSAID<sup>\*1</sup> conjugates)

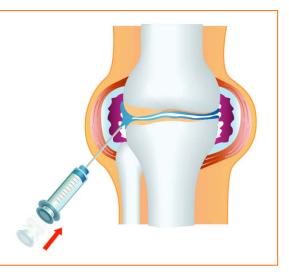
Indication: Knee Osteoarthritis

Formulation: Injection into knee joint

**Current stage:** 

**Japan: Pll** 

The next trial is under consideration in light of results obtained in December 2013.



#### Features:

- Hyaluronic acid combined with NSAID for relief of severe pain and inflammation of OA using Seikagaku's unique technology
- Sustained-release\*<sup>2</sup> of the NSAID for long-term improvement of severe pain and inflammation
- Minimal side effects compared to oral or topical treatment of the NSAID
- \*1 NSAID: Non-Steroidial Anti-Inflammatory Drug
- \*<sup>2</sup> Sustained release: Gradual release of active ingredients to produce a sustained therapeutic effect over a long period

### **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



## **Basic Policy on Profit Distribution**

### Dividends

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

\*Accompanying the abolishment of the shareholder benefit plan, we have increased the basic amount by ¥1 per share (released on July 30, 2013)

### 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 (Forecast)	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%

#### **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.





# **Special Profile**

Contributing to medical care in Japan and overseas through three unique features

### **Specialization in glycoscience**

- 1st Niche field, market not big enough for the major pharmaceutical companies to penetrate
  - Focusing on this field more than 60 years

# 2nd Unique business model Concentration on R&D and manufacturing

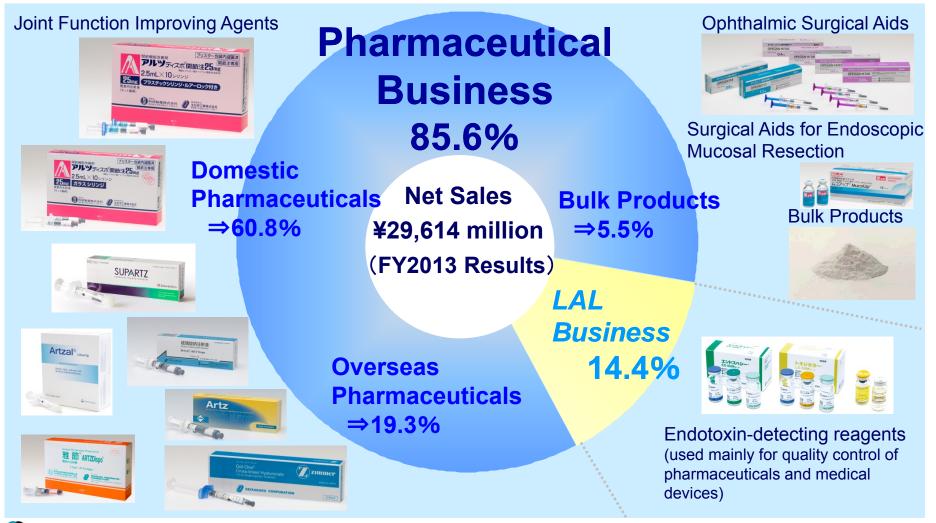
- R&D staff comprising **one-third** of our total employees
- Allocation of over 20% of net sales to R&D investment

### High-level extraction & purification technologies

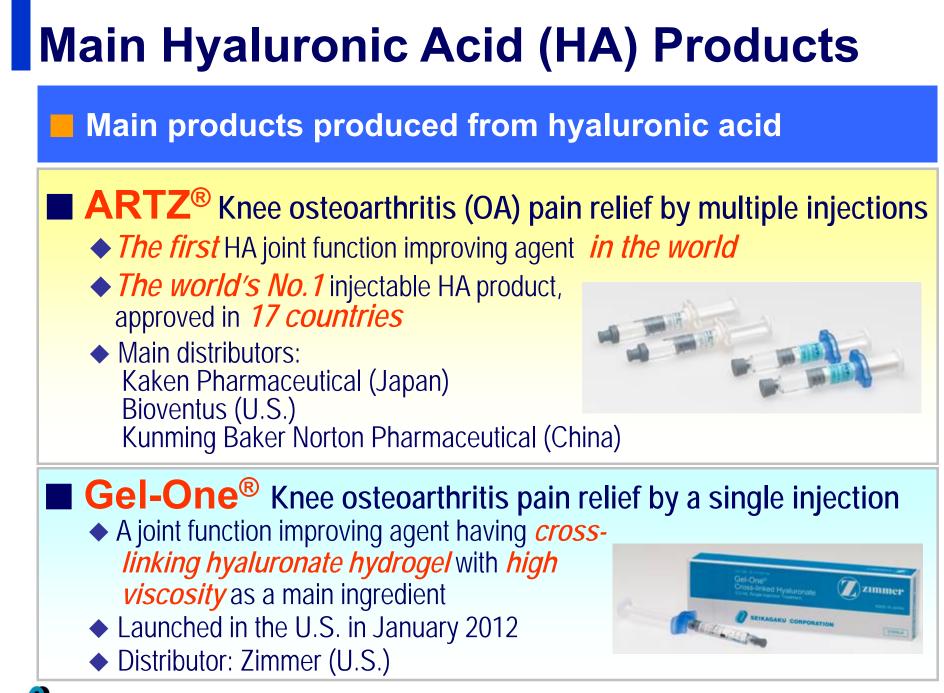
ARTZ ® (main product) has been administered in more than **330** *million* injections without major side effects over more than 25 years

# **Our Business Segment**

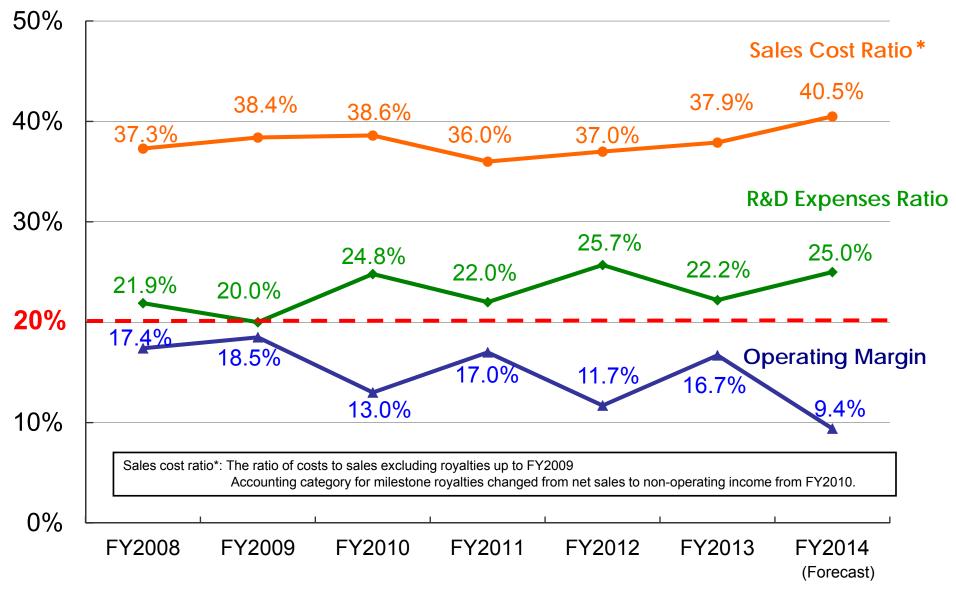
### Pharmaceuticals are our core, making up 85% of net sales



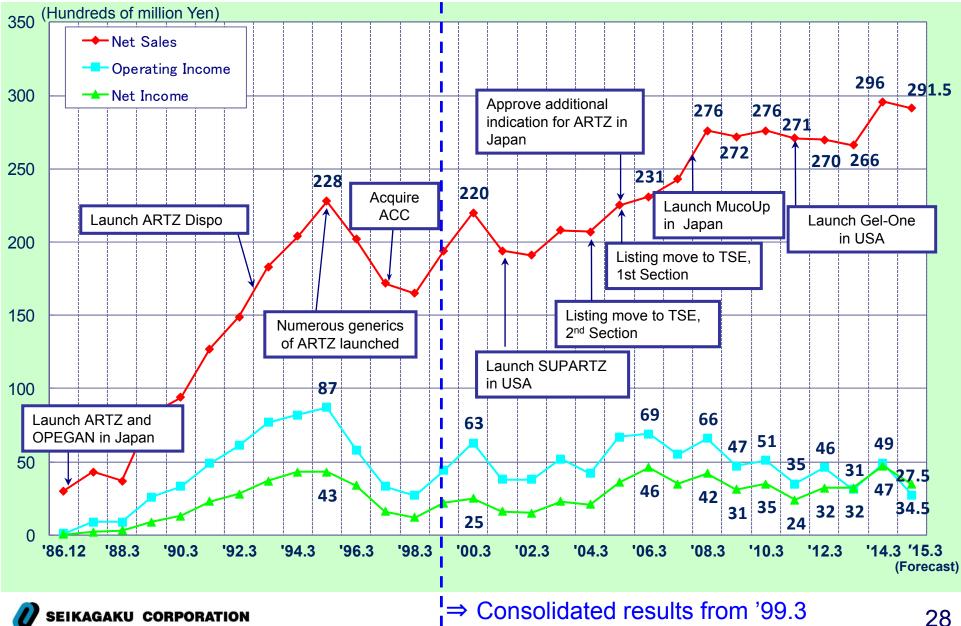
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# **Trend in Financial Index**

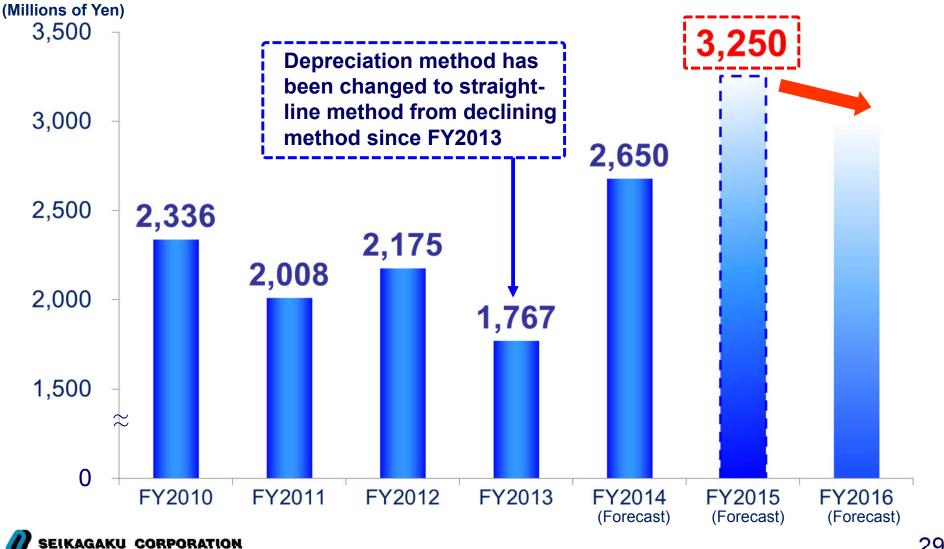


## **Business Progress & Highlights**

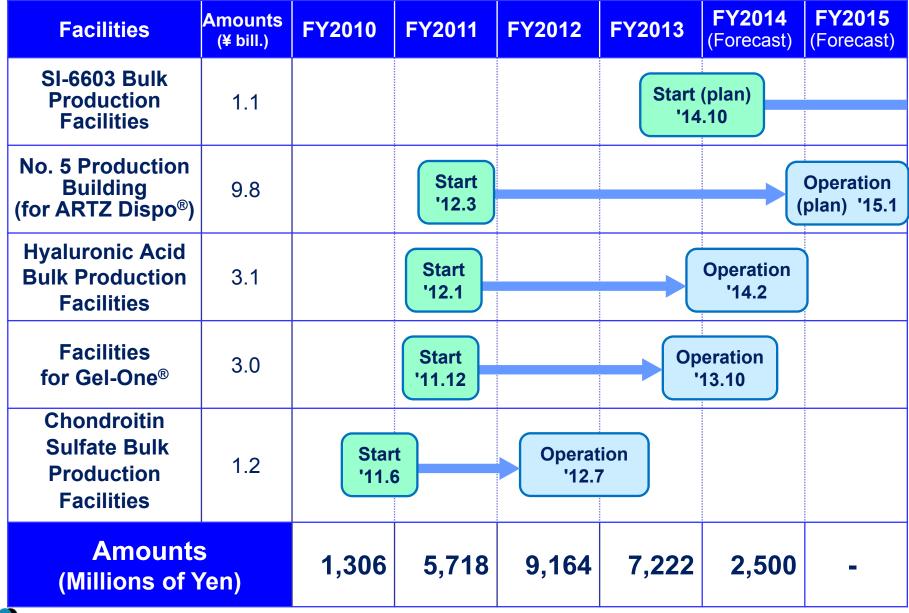


### **Trend in Depreciation**

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



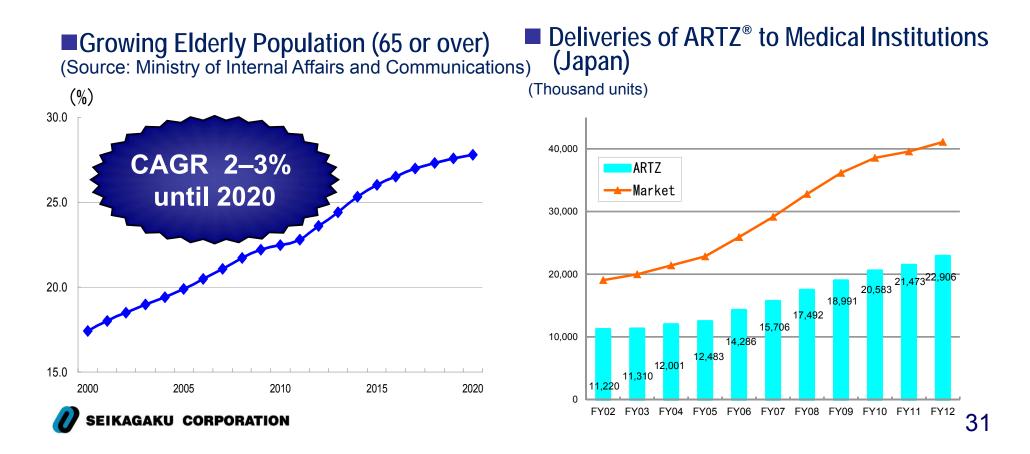
## **Trend in Capital Investments**



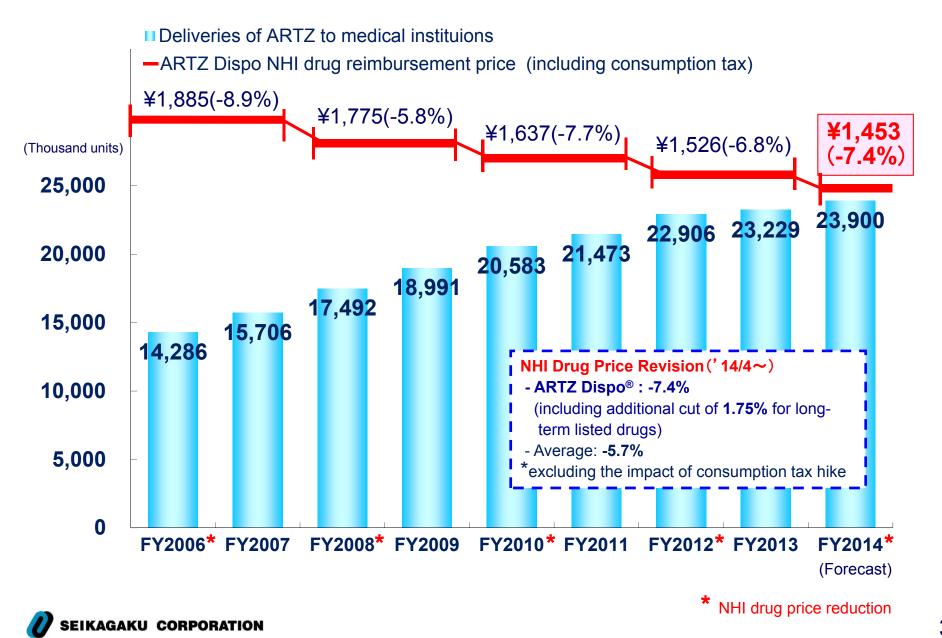
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### **Market Environment for ARTZ® in Japan**

- 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



### Market Expansion through Disease Awareness Campaigns

#### Ads placed in local newspapers (8 times in 7 papers)



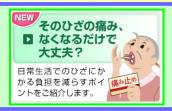
# A web-based survey and media seminars to promote early medical examinations



"Fact-Finding Survey of Knee Pain Experienced in Everyday Life and Medical Examination Awareness" targeting 519 examined and 518 unexamined patients with knee pain indicating initial symptoms of osteoarthritis of the knee ⇒ Articles published in 31 newspapers and other publications

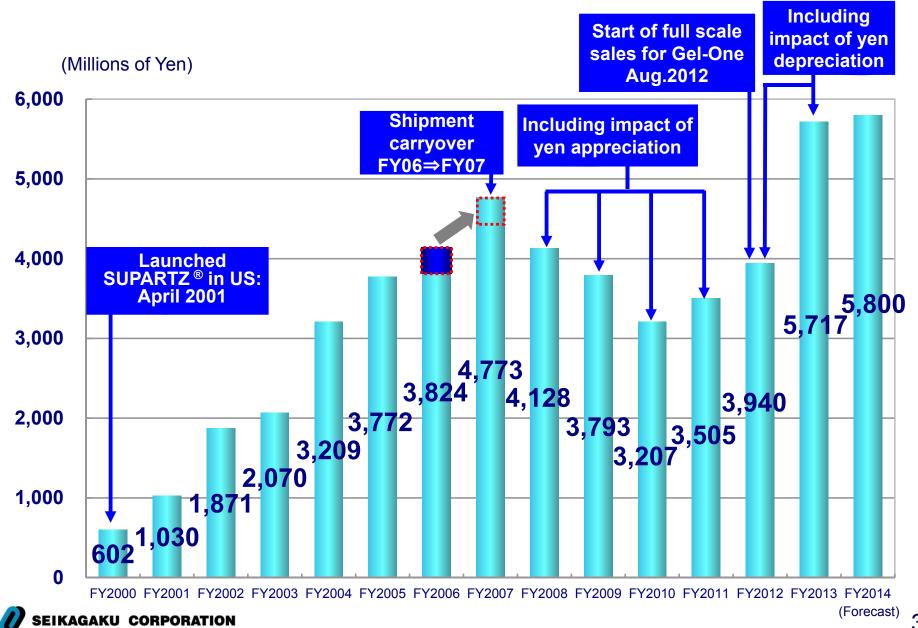


Addition of new content to enhance information on the disease awareness website



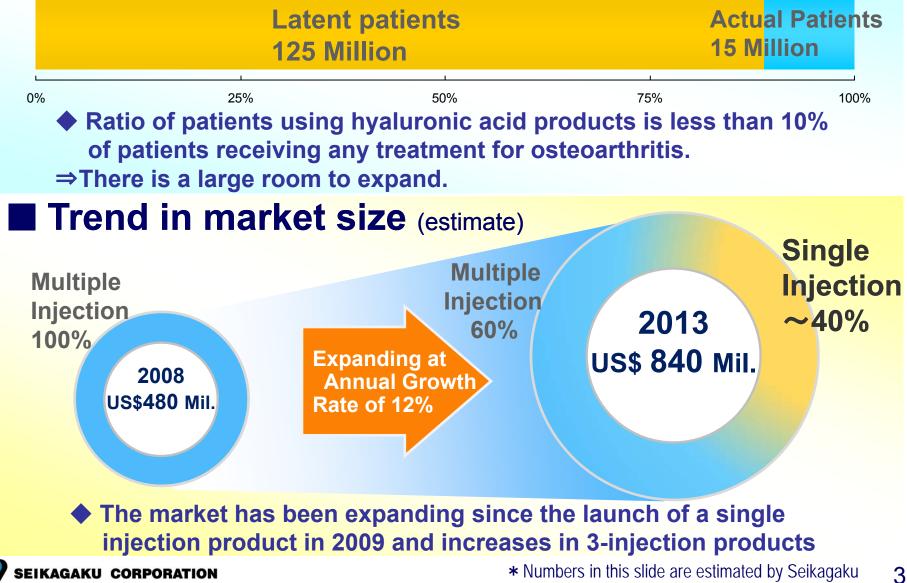


### **Trend in Hyaluronic Acid Products in Overseas Market**



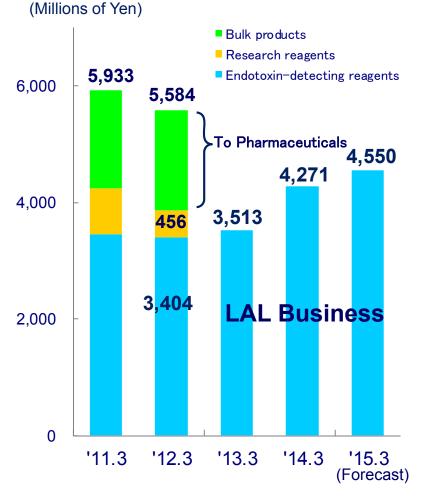
## U.S. Market for Hyaluronic Acid Products

### Number of osteoarthritis patients (estimate)



## Sales of LAL Business (Value Basis)

#### **Sales of LAL Business**



#### FY2013 Results: +21.6%(year-on-year)

Japan:	Increases in reagents for quality
	control and related equipment
Overseas	s: Sales of ACC, a U.S. subsidiary ACC,
	increased due to an increase in
	endotoxin reagents and impact of
	yen depreciation

#### 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

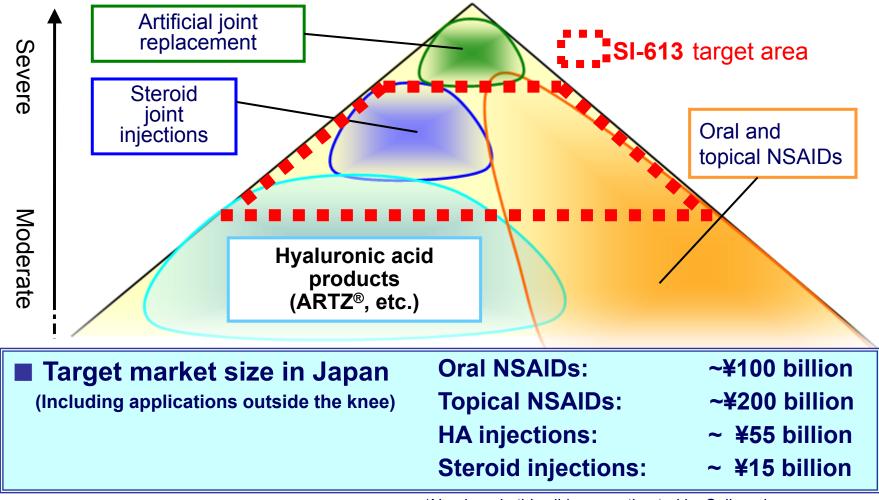
#### Segment Changes

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 endotoxin-detecting 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



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# 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

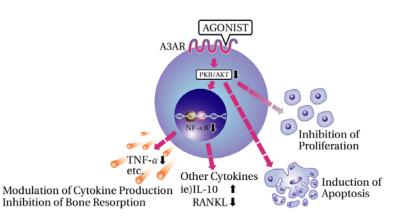
- Substance: Adenosine A3 receptor agonist
  - Indication: Rheumatoid arthritis
- Formulation: Oral agent
- Current stage:



Phase I single administration clinical trial completed in May 2009

Europe : PIIb

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.

#### **Cautionary statement regarding forward-looking information**

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