# **Financial Results** for the Fiscal Year 2012 (April 1, 2012 - March31, 2013)

Exploring the Innovative Promise of Glycoscience





**SEIKAGAKU CORPORATION** 

(TSE: 4548)

# Financial Results for FY2012

(Millions of yen)

	FY2012 Results	FY2011 Results	vs. Previous Year	Forecast Nov.6,2012 Announcement	vs. Forecast	
Net Sales	26,639	27,082	<b>-443</b> (-1.6%)	26,750	<b>-110</b> (-0.4%)	
Operating Income	3,126	4,617	<b>-1,490</b> (-32.3%)	2,700	<b>+426</b> (+15.8%)	
Ordinary Income	4,302	4,770	<b>-468</b> (-9.8%)	3,550	<b>+752</b> (+21.2%)	
Net Income	3,256	3,270	<b>-13</b> (-0.4%)	2,700	<b>+556</b> (+20.6%)	
R&D Expenses	6,838	5,970	<b>+867</b> (+14.5%)	6,700	+138 (+2.1%)	
R&D Expenses Ratio (to Net Sales)	25.7%	22.0%	+3.7pt	25.0%	+0.7pt	
Net Income Per Share	¥57.33	¥57.58	-¥0.25	¥47.53	+¥9.80	

Average Exchange Rate (1US\$)

SEIKAGAKU CORPORATION

¥83.11

¥79.07

¥78.00 (2<sup>nd</sup> half assumption)

## Net Sales in FY2012 (Year-on-Year)

Net sales: ¥26,639 (-¥443, -1.6%)

(Millions of yen)

[Pharmaceuticals: ¥23,125 (-¥96)]

- Japan (-¥225)

ARTZ®: Higher deliveries to medical institutions and market share

Seikagaku sales up, with a volume increase compensating for NHI drug price reductions

OPEGAN®: Share decrease due to continued intense competition, despite higher deliveries to

medical institutions

Seikagaku sales down due to NHI drug price reductions and inventory adjustments

by the sales partner

MucoUp®: Seikagaku sales up due to successful measures to penetrate endoscopic surgery

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

- **Overseas**(+¥435)

ARTZ®: -U.S.; Lower local sales of SUPARTZ due to an increasing numbers of insurance companies

restricting reimbursement

-China; Substantial sales increase on strong local sales

Gel-One®: Start for full-scale sales activities following the winning patent infringement lawsuit in

August 2012

- Bulk Products (-¥306): Decrease following a high level of shipments of hyaluronic acid in FY2011

[LAL: ¥3,513 (-¥346)] Decrease due to discontinuation of the research reagents business

Decrease in sales due to discontinuation of the research reagents business, even though sales volume increases for ARTZ in Japan and overseas and for Gel-One mostly compensated for NHI drug price reductions

## Income in FY2012 (Year-on-Year)

(Millions of yen)

### Operating Income: ¥3,126 (-¥1,490, -32.3%)

#### [Cost of Sales (+¥119)]

- \*Cost of sales ratio: 37.0% (+1.0pt.)
- A slight increase due to factors including NHI drug price reductions, despite a cost of sales ratio decrease resulting from discontinuation of the research reagents business and higher production

### [SG&A expenses (+¥928)]

R&D expenses: ¥6,838 (+¥867)

- Progress with SI-613 and other development themes and higher depreciation of new facilities

## Net Income: ¥3,256 (-¥13, -0.4%)

### [Non-Operating Income/Expenses (+¥1,022)]

Increase in royalty income (+¥610)

Impact of yen depreciation on valuation of foreign currency-denominated assets (+¥312)

### [Extraordinary losses (-¥82)]

Non-recurrence of losses from the earthquake

- \*Decrease in tax expense from application of preferential taxation due to designation of the Takahagi Plant as a special district for industrial revitalization
- Net income at the prior-year level, as a result of an increase in royalty income and the application of preferential taxation related to the earthquake, despite a decrease in operating income due to higher R&D expenses and other SG&A expenses



# Net Sales by Business Segment

(Millions of yen)

LAL Business: 13.2%(-1.1pt)

**Net Sales** ¥26,639 mil.

Pharmaceuticals: 86.8%(+1.1pt) Domestic Pharmaceuticals: 66.7% Overseas Pharmaceuticals: 14.8% **Bulk Products:** 5.3%

25%

Segment	Net Sales	vs. Previous Period	Change
【Pharmaceuticals】	23,125	-96	-0.4%
Domestic Pharmaceuticals	17,767	-225	-1.3%
Overseas Pharmaceuticals	3,940	+435	+12.4%
<b>Bulk Products</b>	1,417	-306	-17.8%
【LAL Business】	3,513	-346	-9.0%
Total	26,639	-443	-1.6%
(Overseas Sales)	6,311	+276	+4.6%

**Domestic Sales** 76.3%(-1.4pt)

**Overseas Sales** 23.7%(+1.4pt)

SEIKAGAKU CORPORATION

0%

50% **75%** 100%

# Comparison with Forecasts for FY 2012 (announced on Nov. 6, 2011)

(Millions of yen)

### Net sales: ¥26,639 (-¥110, -0.4%)

- Pharmaceuticals (-¥74): Decrease in sales volumes of domestic pharmaceuticals and bulk products, despite the impact of yen depreciation
- LAL (-¥36): Decrease in sales at an overseas subsidiary

### **Operating income: ¥3,126 (+¥426, +15.8%)**

- Cost of sales (approx. -¥300): Decrease accompanying lower sales volumes
- SG&A expenses (approx. -¥200): R&D expenses (+¥138) Forecast ¥6,700 ⇒ Actual: ¥6,838
   ⇒ Steady progress with development themes
   Decrease in other SG&A expenses, including

Gel-One lawsuit expenses

### Net income: ¥3,256 (+¥556, +20.6%)

- Increase in non-operating income: Increase in foreign exchange gains related to valuation of foreign currency-denominated assets, reflecting the impact of yen depreciation
- Net sales nearly in line with the forecast. Income exceeded forecasts due to factors including lower cost of sales and SG&A expenses and the impact of yen depreciation.



# Overview of Forecast for FY2013

(Millions of yen)

	FY2013 Forecast	FY2012 Results	vs. Previous Year
Net Sales	29,900	26,639	<b>+3,260</b> (+12.2%)
Operating Income	4,550	3,126	<b>+1,423</b> (+45.5%)
Ordinary Income	5,000	4,302	<b>+697</b> (+16.2%)
Net Income	4,050	3,256	<b>+793</b> (+24.4%)
R&D Expenses	7,050	6,838	<b>+211</b> (+3.1%)
R&D Expenses Ratio (to Net Sales)	23.6%	25.7%	-2.1pt
Net Income Per Share	¥71.29	¥57.33	¥13.96

Average Exchange Rate (1US\$)

¥95.00 (Assumption)

¥83.11



## Forecasts for FY2013 (Year-on-Year)

### Net sales: ¥29,900 (+¥3,260, +12.2%)

(Millions of yen)

- Domestic pharmaceuticals (approx. +¥1,000): Increase for ARTZ, and steady sales of OPEGAN and MucoUp
- Overseas pharmaceuticals (approx. +¥1,550): Increase for Gel-One and sales to China, with SUPARTZ at the prior-year level
- LAL(approx. +¥600): Increase at ACC sales mainly due to yen depreciation
   \*Impact of yen depreciation on overall net sales (approx. +¥1,150)

### Operating income: ¥4,550 (+¥1,423, +45.5%)

- Cost of sales (approx. +¥1,200): Increase on higher sales volumes
- SG&A expenses (approx. +¥600): R&D expenses: +¥211 (progress with development themes, such as SI-6603 in Japan and the U.S.)

Increase in sales-related expenses such as costs related to Gel-One sales expansion

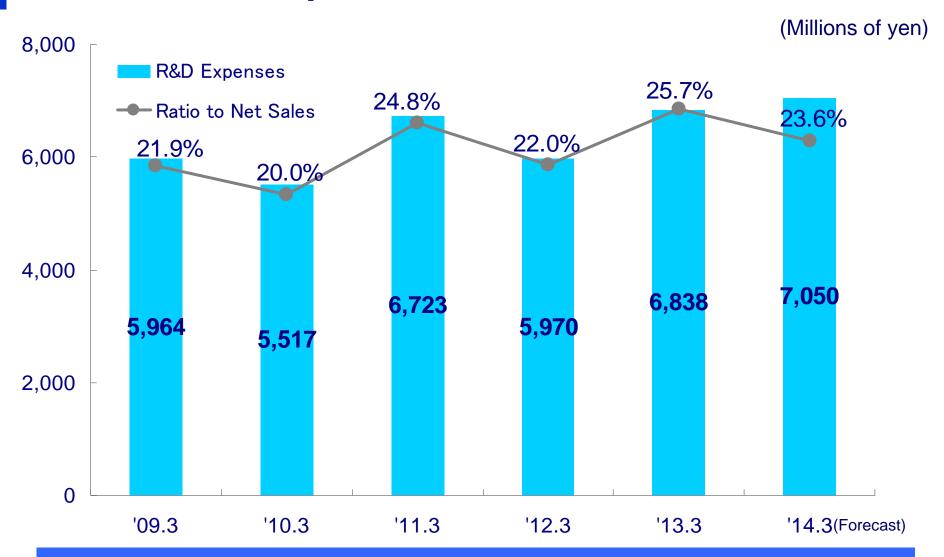
\*Impact on income of change in depreciation method (declining-balance method ⇒ straight-line method (approx. +¥500)

### Net income: ¥4,050 (+¥793, +24.4%)

- Decrease in non-operating income: Decrease in royalty income
- Decrease in tax expense: Due to continuation of preferential taxation because of designation of the Takahagi Plant as a special district for industrial revitalization
- Higher sales and income due to higher sales volumes of ARTZ (Japan and China) and Gel-One<sup>®</sup>, and the impact of yen depreciation, despite higher SG&A expenses



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



R&D expenses for FY2013 at a high level due to progress with development themes such as SI-6603 in Japan and the U.S.

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

#### **ARTZ®** Deliveries to Medical Institutions



#### FY2012 Results (year-on-year)

<<Market>>: +3.8%

 Expansion due to an increase in the aged population and continuous implementation of disease awareness activities ⇒ Higher growth rate

<<ARTZ®>>: **+6.7%** 

- Impact of introduction of a plastic syringe product
- Enhanced brand potential as the original product
  - **⇒** Market share: 55.7%(+1.4 pt.)

#### FY2013 Forecasts (year-on-year)

<<Market>>: +3.8% <<ARTZ®>>: +6.6%

- Continue marketing activities that take advantage of brand strength
- Extend medical specialties on departments other than orthopedic surgery

Drug price revisions (effective April 2012)

- ARTZ Dispo®: ¥1,526 (-6.8%)
- Industry average: -6.2%

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

## Market Expansion through Disease Awareness Campaigns

Ad placement in the nationwide morning edition of the *Asahi Shimbun* (three times a year)

Holding of a public lecture on knee osteoarthritis (September)

Enhancement of information on the disease awareness website





Panel discussion by prominent persons and medical specialists ⇒ 606 participants





Posting of findings of surveys concerning knee pain and ways of coping with it





## Sales of OPEGAN® (unit deliveries to medical institutions)

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



#### FY2012 Results (year-on-year)

<<Market>>: +5.8%

- Expansion due to an increase in the aged population
- Rebound from a decrease in the number of surgeries in FY2011 (impact of the earthquake and power outages)

<<OPEGAN®>>: **+2.6%** 

- Upturn in sales on focused sales promotion activities
- Market share decline due to intensified competition

#### FY2013 Forecasts (year-on-year)

<<Market>>: +3.5%

- Expansion commensurate with the rate of increase in the aged population

<<OPEGAN®>>: +3.5%

- Implementation of measures to strengthen information provision activities
- ⇒Aim for growth in line with market expansion

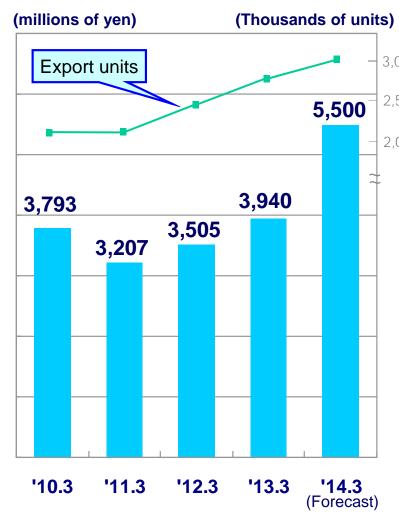
Drug price revisions (effective April 2012)

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

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

## Overseas Pharmaceuticals (value basis)

#### Overseas Pharmaceuticals Sales



#### FY2012 Results: +12.4% (year-on-year)

<<ARTZ® (multiple injection)>>: +7.0% (Seikagaku export sales)

- SUPARTZ in the U.S: Decrease in local sales due to reimbursement restriction by some insurance companies (-5.5%)
- 3,000 ◆ ARTZ in China: Strong local sales sustained (+21%)
- 2,500 ◆ Seikagaku export sales: Sales of ARTZ to China compensate for lower sales of SUPARTZ to the U.S.
- 2,000 << Gel-One® (single injection)>>
  - Start for full-scale sales activities following the winning patent infringement lawsuit August 2012
  - Seikagaku export sales: Resumption of shipments last October

### FY2013 Forecast: +39.6% (year-on-year)

(Impact of yen depreciation in the above forecast:+16.5%)

- <<ARTZ® (multiple injection)>>: +10.3% (Seikagaku export sales)
- ◆ SUPARTZ in the U.S.: Continued severe business environment due to strict reimbursement
- ◆ ARTZ in China: Continued strong sales
- Seikagaku export sales: Sales increase as shipments of ARTZ to China compensate for lower shipments of SUPARTZ to U.S.
- <<Gel-One® (single injection)>>
- Substantial increases in local sales and Seikagaku export sales due to expansion of sales channel



## Sales and Manufacturing Strategy of Gel-One® in the U.S.

Sales Promotion in the U.S.

# <<Measures by Zimmer to Expand Sales Channels>>

- Contract signed with major pharmaceutical distributors
- Public insurance reimbursement price obtained
- Toward inclusion on reimbursement lists of private insurance companies



< Gel-One®, a single injection product for knee osteoarthritis pain>

Approval: March 2011Launch: January 2012

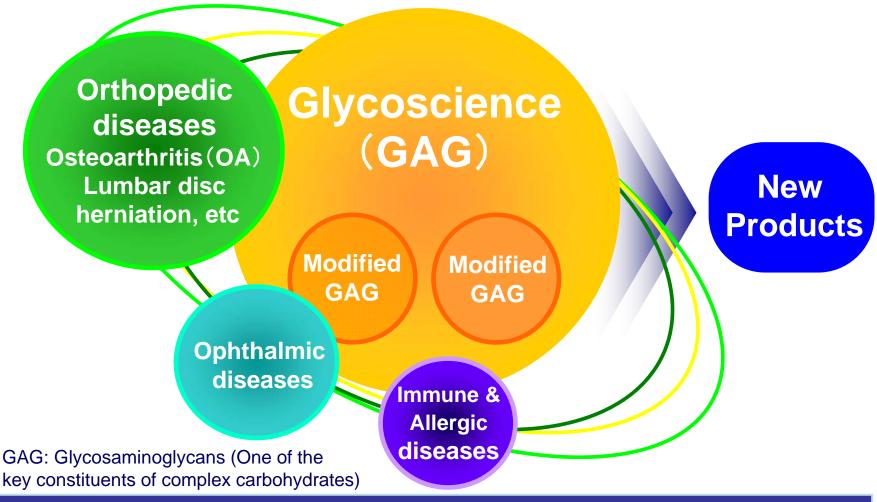
### << Differentiation from Competitors>>

- Demonstrates effectiveness with a single, small-volume injection (3ml)
- Safety demonstrated in clinical trials
- Production System Establishment
  <<Construction of dedicated production</p>
  facilities for Gel-One®>>
  - Completion of construction in Sep. 2012 (investment: ¥3.2 billion)
  - Operation scheduled to begin in Jan. 2014



Constructed in the No.3 Production Building at the Takahagi Plant

## **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	ΡI	PΙ	РШ	Applic ation
SI-6603	Lumber Disk	Japan				
Condoliase	Herniation	U.S.				
SI-657 Hyaluronic Acid	Enthesopathy Additional indication for ARTZ	Japan				
SI-613 Hyaluronic Acid-NSAID conjugates	Knee Osteoarthritis	Japan				
SI-614 Modified Hyaluronate	Dry eye	U.S.				
SI-615 Adenosine A3 receptor agonist	Rheumatoid Arthritis	Japan				





## SI-6603 Outline

◆Substance: Condoliase

◆Indication: Lumber disc herniation

◆Method of use: Injection into lumber disc

(under X-ray observation)

### [Current Stage]

Japan: PIII

March 2012: Case registration started
 February 2013: Case registration completed

Within FY2013: NDA application expected

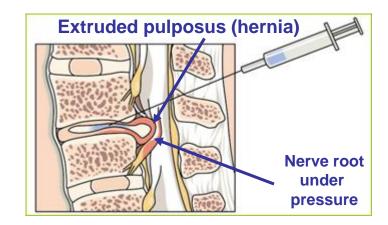
## **United States: PIII**

August 2012: Phase II completed

April 2013: Phase III started

#### 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.



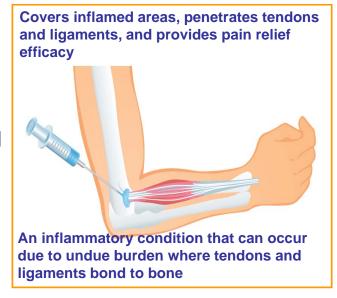
## SI-657 Outline

- ◆ **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

Japan: PIII

◆ October 2012: Late Phase II completed

May 2013: Phase III started



#### 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)



# SI-613 Outline

◆ Substance: SI-613

(Hyaluronic acid-NSAID\* conjugates)

◆ Indication: Knee Osteoarthritis

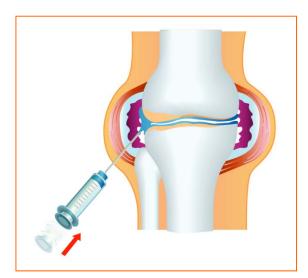
◆ Formulation: Injection into knee joint

### [Current Stage]

Japan: Pll

◆ October 2012 : PI completed

March 2013: PII started



#### Features

- Having the pain relief and anti-inflammatory effect of an NSAID, in addition to the joint function improving effect of hyaluronic acid
- Sustained-release of the NSAID for prompt and long-term improvement of severe pain and inflammation
- By administrating directly into the joint cavity, mitigation of side effects expected compared to oral or topical treatment of the NSAID
- Global development including the U.S. and other areas

<sup>\*</sup> NSAID: Non-Steroidial Anti-Inflammatory Drug



## SI-614 Outline

◆ Substance : SI-614 (Modified Hyaluronate)

◆ Indication: Dry eye

◆ Formulation : Ophthalmic solution

#### [Current Stage]

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

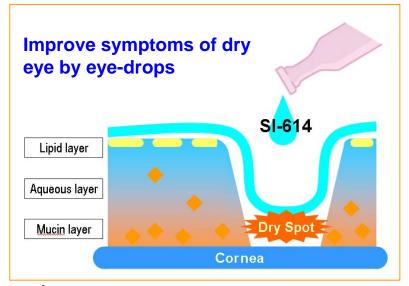
◆ March 2012: Start of case registration

September 2012: Phase II clinical trial completed

⇒next clinical trial now under consideration since a clinically useful effect was confirmed

#### **♦** Features:

- SI-614 is a modified hyaluronate produced by Seikagaku's proprietary technology and it is expected to improve symptoms of dry eye by protection of ocular surface and promotion of corneal epithelial wound healing 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

Ten-Year Vision "Global Category Pharma"

Converge major R&D resources on Glycoscience and Establish Global Competitiveness

## ACT for the future

Advance · Challenge · Transparency

Development of new buds for Achieving the Ten-Year Vision

Step 2

2009 2012
Fostering of basic corporate
strength and development
of core systems

Step 1

2015

2018

**Vision realization** 

Step 3



# **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-to-long term perspective

## **♦ Flexible Capital Policy**

Share buy-back is an option for improving capital efficiency

	FY2009	FY2010	FY2011	FY2012 (Forecast)	FY2013 (Forecast)
Net Income per share	¥62.94	¥43.16	¥57.58	¥57.53	¥71.29
Annual Total Dividend	¥25.00	¥25.00	¥25.00	¥25.00	¥25.00
Dividend Payout Ratio	39.7%	57.9%	43.4%	43.6%	35.1%



#### Exploring the Innovative Promise of Glycoscience

#### Cautionary statement regarding forward-looking information

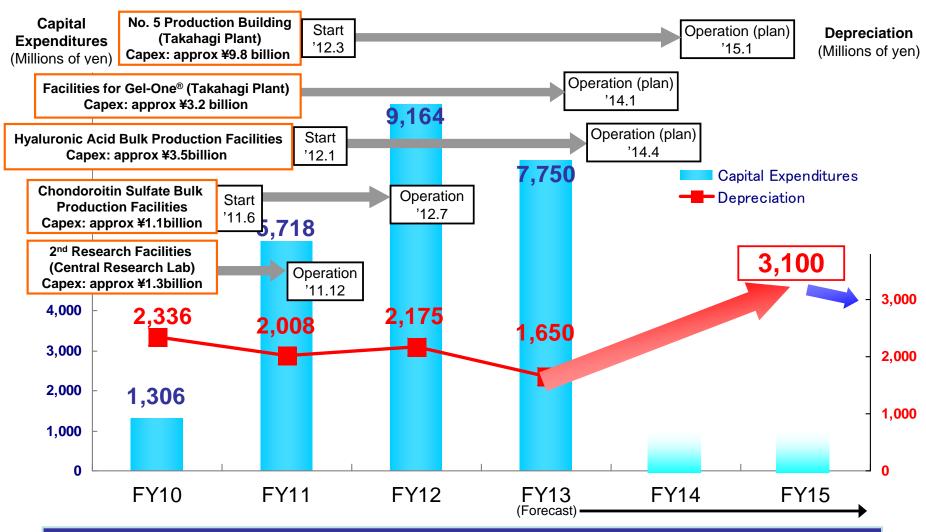
This material includes forward-looking statements based on assumptions and beliefs in light of the information currently available to management and subject to significant risks and uncertainties. Actual financial results may differ materially depending on a number of factors including adverse economic 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.





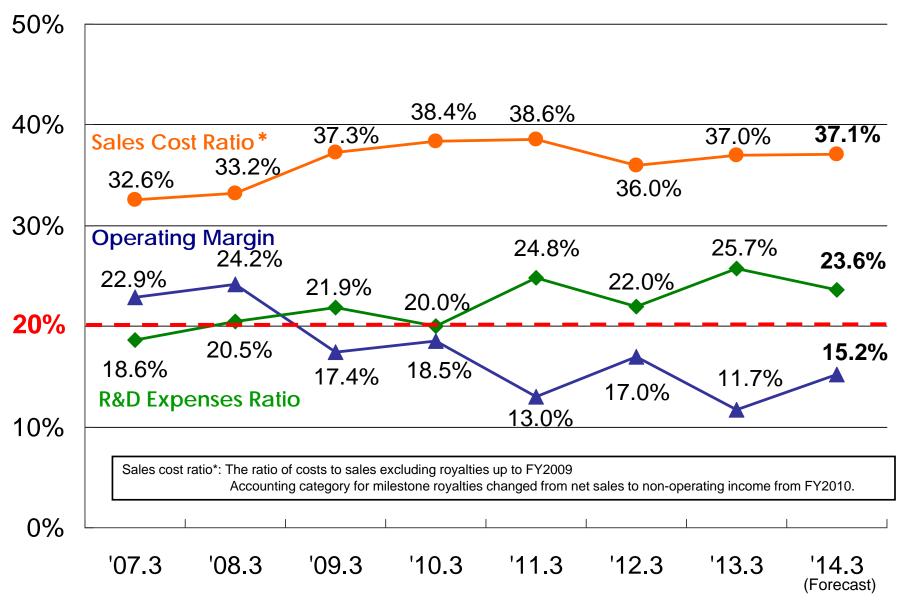
### Mid-term Management Plan: Trend in Capital Expenditures and Depreciation



Depreciation will increase due to implementing large and active capital expenditures
 Peak figures will be decreased from ¥3.5 billion to ¥3.1 billion by the change of the depreciation method

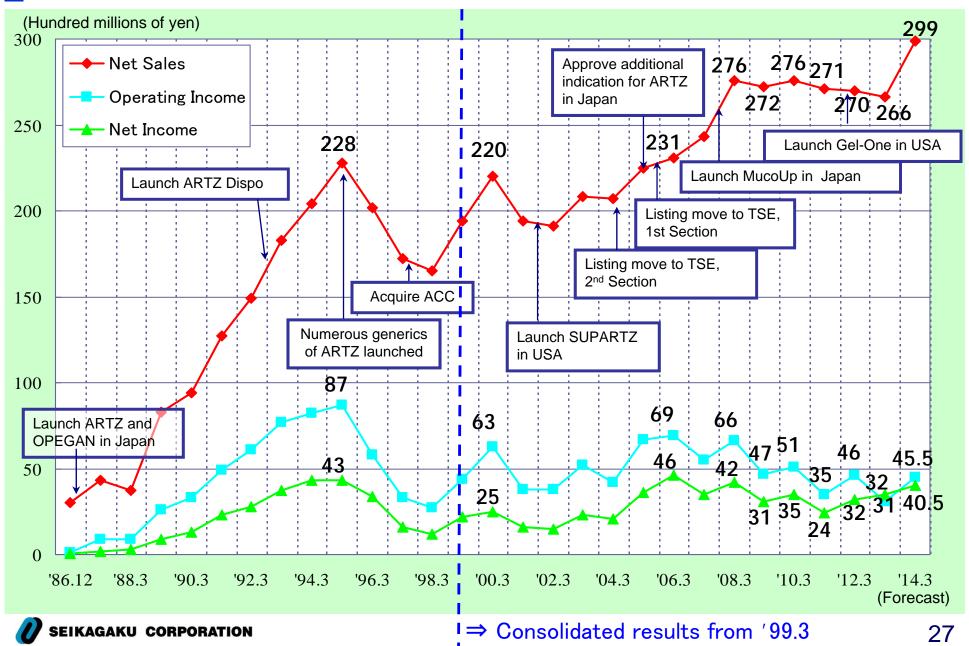


## Trend in Financial Index



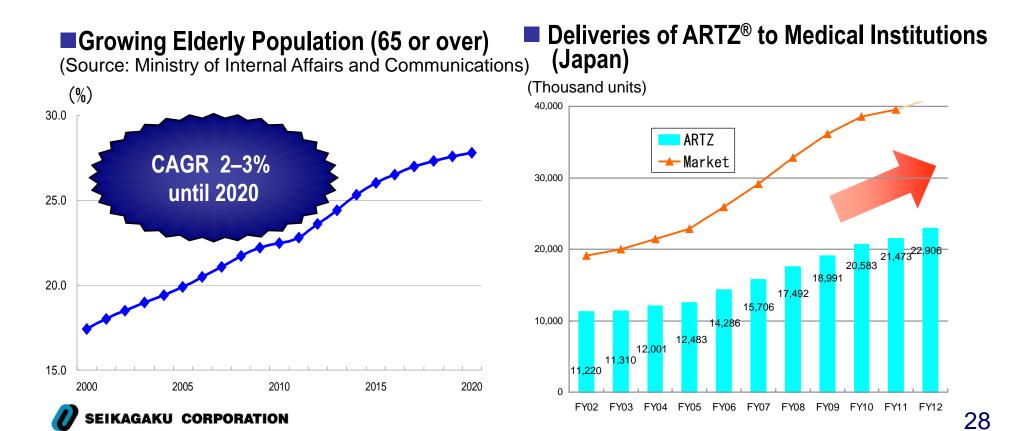


# **Business Progress & Highlights**



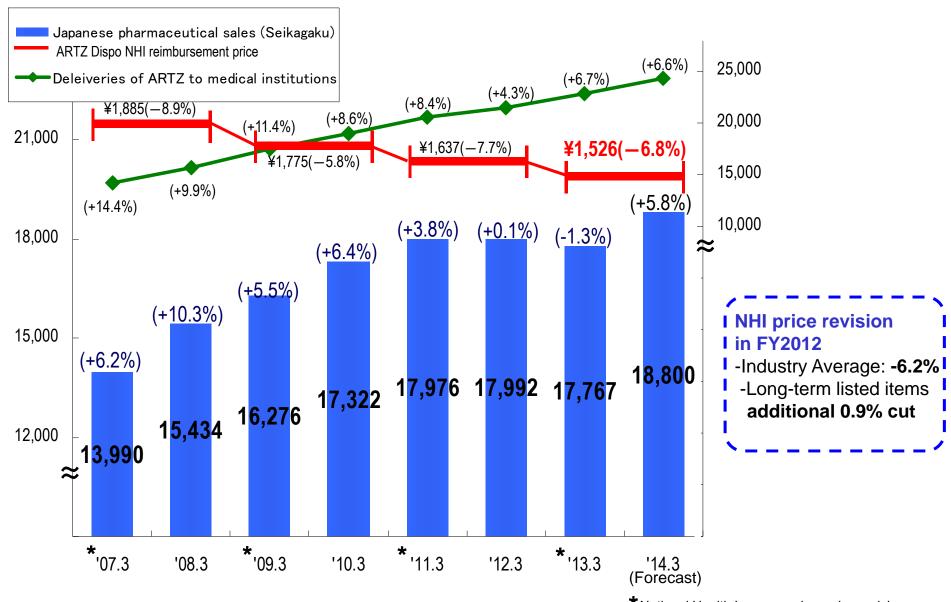
## **Expanding Market of ARTZ® in Japan**

- 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)

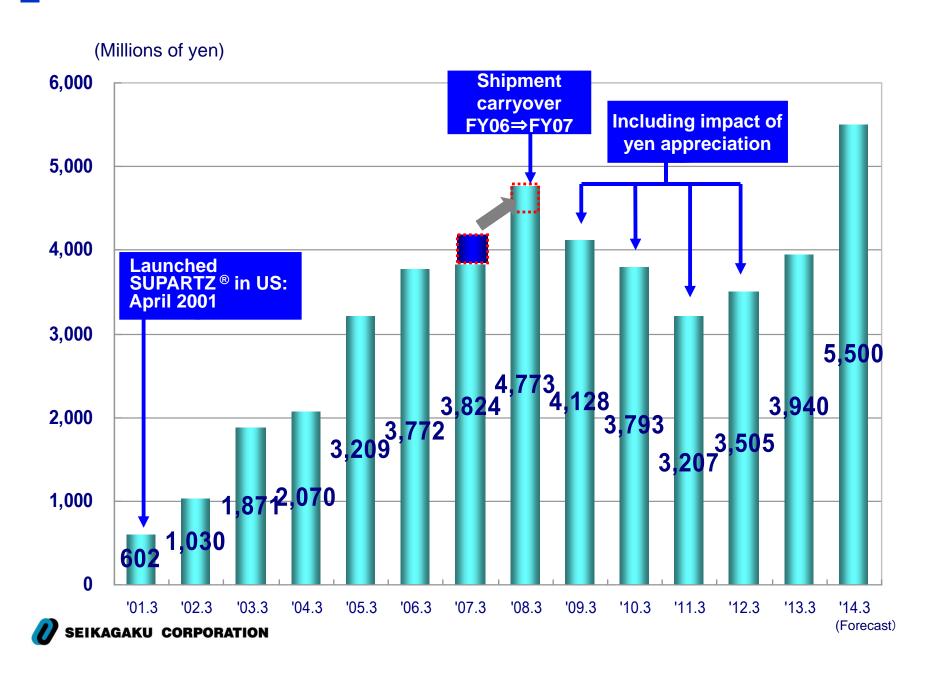


## Trend in NHI Reimbursement Price and Our Domestic Pharmaceuticals Sales

KAGAKU CORPORATION

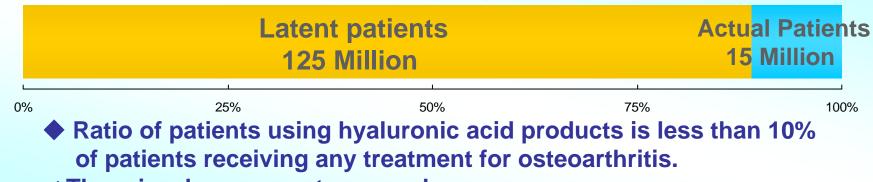


## Trend in Hyaluronic Acid Products in Overseas Market



## U.S. Market for Hyaluronic Acid Products

■ Number of osteoarthritis patients (estimate)

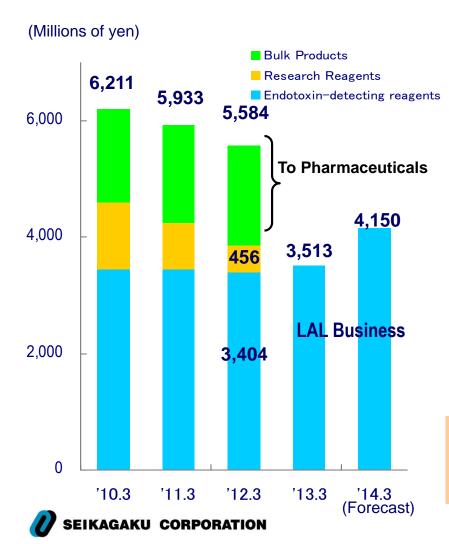


⇒There is a large room to expand.



## Sales of LAL Business (Value Basis)

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



# FY2012 Result: -9.0% (year-on-year)

<< Endotoxin-detecting reagents>>: +1.9%

Japan: Firm sales of reagents for pharmaceuticals quality control and for dialysis fluid quality management Overseas: Decrease in sales of reagents for quality control

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

⇒ Impact of approx. -¥0.4 billion

# ■ FY2013 Forecasts: +18.1% (year-on-year)

Japan: Sales at the prior-year level

Overseas: Sales increase at U.S. subsidiary ACC,

partly attributable 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-615 Outline

Substance: Adenosine A3 receptor agonist

Indication: Rheumatoid arthritis

Formulation: Oral agent

♦ Origin: In-license from

Can-Fite BioPharma Ltd.

◆Status: Phase I in Japan

Phase II b in Europe, etc. implemented by Can-Fite

⇒ Seikagaku will reassess its future development policy based on

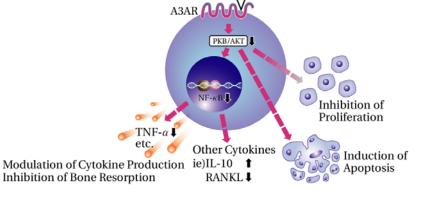
progress with the PIIb mono-therapy trial that is currently being

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.





AGONIST

#### 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.

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