

# Exploring the Innovative Promise of Glycoscience



## Financial Results for the 1H of FY2010

(April 1, 2010-September 30, 2010)



**SEIKAGAKU CORPORATION**

(TSE:4548)

# Financial results for 1H FY2010 (Comparison with 1H FY2009 and initial forecast)

(Millions of Yen)

	FY 2010 1H Results	FY 2009 1H Results	vs. Previous Period	Initial Forecast for 1H	vs. Initial Forecast for 1H
Net Sales	13,882	13,965	-83 (-0.6%)	14,000	-117 (-0.8%)
Operating Income	1,799	2,862	-1,062 (-37.1%)	2,100	-300 (-14.3%)
Ordinary Income	1,717	2,790	-1,073 (-38.5%)	2,200	-482 (-21.9%)
Net Income	1,178	1,894	-716 (-37.8%)	1,500	-321 (-21.5%)
R&D Expenses	3,484	2,703	+781 (+28.9%)	3,100	+384 (+12.4%)
R&D Expenses Ratio (to Net Sales)	25.1%	19.4%	+5.7pt	22.1%	+3.0pt
Net Income per Share	¥20.74	¥33.35	-¥12.61	¥26.40	-¥5.66

Average exchange rate for  
period(1US\$)

¥88.95

¥95.50

¥92.00 (Forecast)

# Net Sales for 1st Half of FY2010 (Year ending March 2011)

**Net sales: ¥13,882 million (-¥83 mil./-0.6%)**

(Year-on-year Comparison)

**[Pharmaceuticals: ¥11,054 million (+¥181 mil.)]**

- Domestic (+¥755 mil.)

Growth in ARTZ sales outweighed the effect of reduced NHI reimbursement price.

- Overseas (-¥573 mil.)

U.S.: Sales lower due to lower volumes resulting from tightening of reimbursement criteria by some private health insurers, and due to high yen

China: Sales higher because of increased local sales.

Negative impact of one-time royalty revenue in 2009/1H

**[Fine chemicals: ¥2,828 million (-¥264 mil.)]**

Research reagents and diagnostics (-¥17 mil.):

Impact of high yen and lower domestic sales (ACC sales higher in local currency)

Active pharmaceutical ingredients (-¥247 mil.):

Shipments of hyaluronic acid postponed to 3rd quarter or later

◆**Point:** Net sales were close to the level of the previous year. Higher domestic sales volume of ARTZ offset NHI price cuts and declines in overseas pharmaceuticals sales (including one-time royalty) and active pharmaceutical ingredients.

# Income for 1st Half of FY2010 (Year ending March 2011)

(Year-on-year Comparison)

## Operating income: ¥1,799 million (-¥1,062 mil./-37.1%)

### **[Cost of sales (+¥285 million)]**

Volume growth in domestic sales of ARTZ

Cost of sale ratio: Increased to 39.0% (+1.5pt) because of drug price cuts (excluding royalties)

### **[SG&A expenses (+¥693 million)]**

R&D expenses: ¥3,484 million (+¥781mil.)

Increase include clinical trials in Japan for SI-6603 and its trial manufacturing costs.

Other expenses lower

## Net income: ¥1,178 million (-¥716 mil./-37.8%)

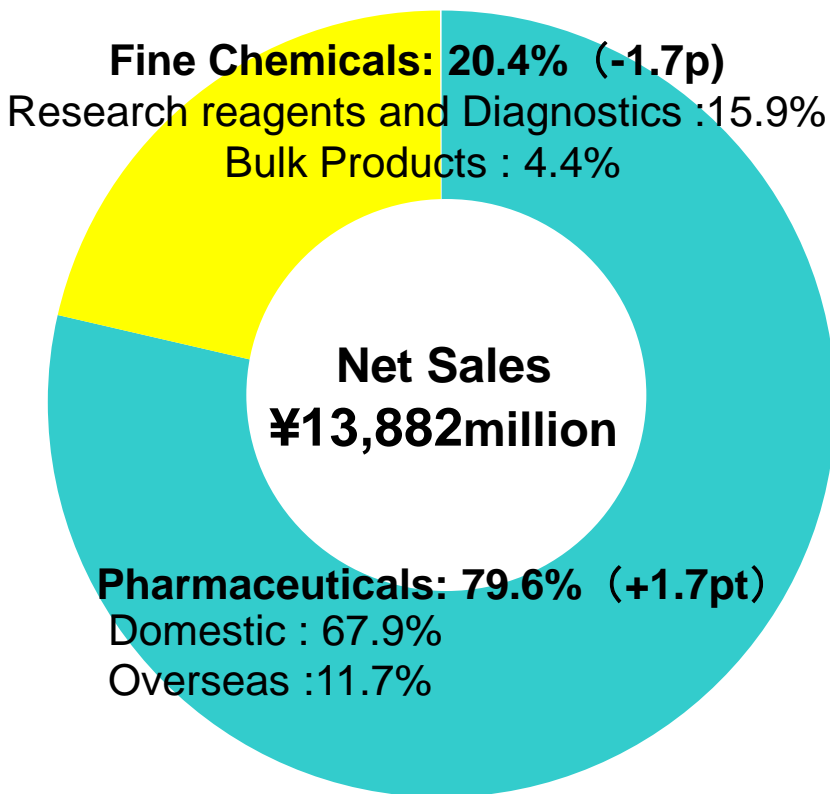
**[Non-operating income (-¥10 mil.)]** Similar to previous year's level

**[Extraordinary losses (+¥51 mil.)]** Retroactive posting of asset retirement obligation expenses (change in accounting standards)

◆**Point:** In addition to cost increases proportionate to volume growth in ARTZ sales, the lower income figure also reflects an increase in R&D expenses resulting from progress with SI-6603.

# Net Sales by Business Segment

(Millions of Yen)



Segment	Net Sales	vs. Previous Period	Change
<b>【Pharmaceuticals】</b>	<b>11,054</b>	<b>+181</b>	<b>+1.7%</b>
Domestic Pharmaceuticals	<b>9,424</b>	<b>+755</b>	<b>+8.7%</b>
Overseas Pharmaceuticals	<b>1,630</b>	<b>-573</b>	<b>-26.0%</b>
<b>【Fine Chemicals】</b>	<b>2,828</b>	<b>-264</b>	<b>-8.6%</b>
Research reagents and Diagnostics	<b>2,211</b>	<b>-17</b>	<b>-0.8%</b>
Bulk Products	<b>616</b>	<b>-247</b>	<b>-28.6%</b>
<b>Total</b>	<b>13,882</b>	<b>-83</b>	<b>-0.6%</b>
(Overseas Sales)	<b>2,943</b>	<b>-481</b>	<b>-14.1%</b>

**Domestic Sales**  
78.8% (+3.3pt)

**Overseas Sales**  
21.2% (-3.3pt)

0%

25%

50%

75%

100%

# FY2010 1st Half Results—Comparison with Initial Forecasts

## Net sales: ¥13,882 million (-¥117mil./-0.8%)

- Pharmaceuticals (+254 mil.): Higher domestic sales led by strong demand for ARTZ.
- Fine chemicals (-¥471 mil.): Reduced domestic sales of reagents and postponement of hyaluronic acid shipments to 3rd quarter or later

## Operating income: ¥1,799 million (-¥300 mil./-14.3%)

- SG&A expenses (approx. +¥200 mil.): Increase in R&D expenses (+¥384 mil.), ¥3,484 mil. versus forecast of ¥3,100 mil.  
Increase include clinical trials in Japan for SI-6603 and its trial manufacturing costs  
Sales-related expenses lower

## Net income: ¥1,178 million (-¥321 mil./-21.5%)

- Increase in non-operating expenses: Higher currency exchange losses relating to valuation of foreign currency-denominated assets and other factors

◆ **Point:** Despite higher domestic sales of ARTZ, sales fell slightly short of the forecast because of reduced sales of fine chemicals. Income was lower than forecast because of increased R&D expenses.

# Overview of Forecast for FY2010 (year-on-year)

(Millions of Yen)

	<b>FY2010</b> Revised forecast	<b>FY2009</b> Results	<b>vs. Previous</b> <b>Year</b>	<b>FY2010</b> Initial forecast	<b>vs. Initial</b> <b>forecast</b>
<b>Net Sales</b>	<b>27,200</b>	<b>27,617</b>	<b>-417</b> (-1.5%)	<b>27,800</b>	<b>-600</b> (-2.2%)
<b>Operating Income</b>	<b>3,300</b>	<b>5,110</b>	<b>-1,810</b> (-35.4%)	<b>3,900</b>	<b>-600</b> (-15.4%)
<b>Ordinary Income</b>	<b>3,400</b>	<b>5,114</b>	<b>-1,714</b> (-33.5%)	<b>4,100</b>	<b>-700</b> (-17.1%)
<b>Net Income</b>	<b>2,700</b>	<b>3,575</b>	<b>-875</b> (-24.5%)	<b>3,000</b>	<b>-300</b> (-10.0%)
<b>R&amp;D Expenses</b>	<b>6,900</b>	<b>5,517</b>	<b>+1,382</b> (+25.1%)	<b>6,600</b>	<b>+300</b> (+4.5%)
<b>R&amp;D Expenses Ratio</b> (to Net Sales)	<b>25.4%</b>	<b>20.0%</b>	<b>+5.4pt</b>	<b>23.7%</b>	<b>+1.7pt</b>
<b>Net Income per Share</b>	<b>¥47.53</b>	<b>¥62.94</b>	<b>-¥15.41</b>	<b>¥52.81</b>	<b>-¥5.28</b>

Average exchange rate  
for period (1US\$)

¥83.00  
(2nd half forecast)

¥92.86

¥92.00  
(Full year forecast)

# Revised FY2010 Forecasts—Comparison with Initial Forecasts

## Net sales: ¥27,200 million (-¥600 mil./-2.2%)

**[Positive factors]** Increased domestic pharmaceuticals sales  
(Impact of a new competing product on OPEGAN smaller than initially forecast)

**[Negative factors]** Lower overseas sales by high yen (-¥350 mil.)  
Declines in sales of domestic sales of reagents

## Operating income: ¥3,300 million (-¥600 mil./-15.4%)

- SG&A expenses (approx. +¥150 mil.):
  - Increase in R&D expenses (+¥300 mil.)
    - Initial forecast: ¥6,600 mil.; revised forecast: ¥6,900 mil.
    - Higher trial manufacturing costs for SI-6603 and progress on other R&D projects
    - Lower forecast for other expenses

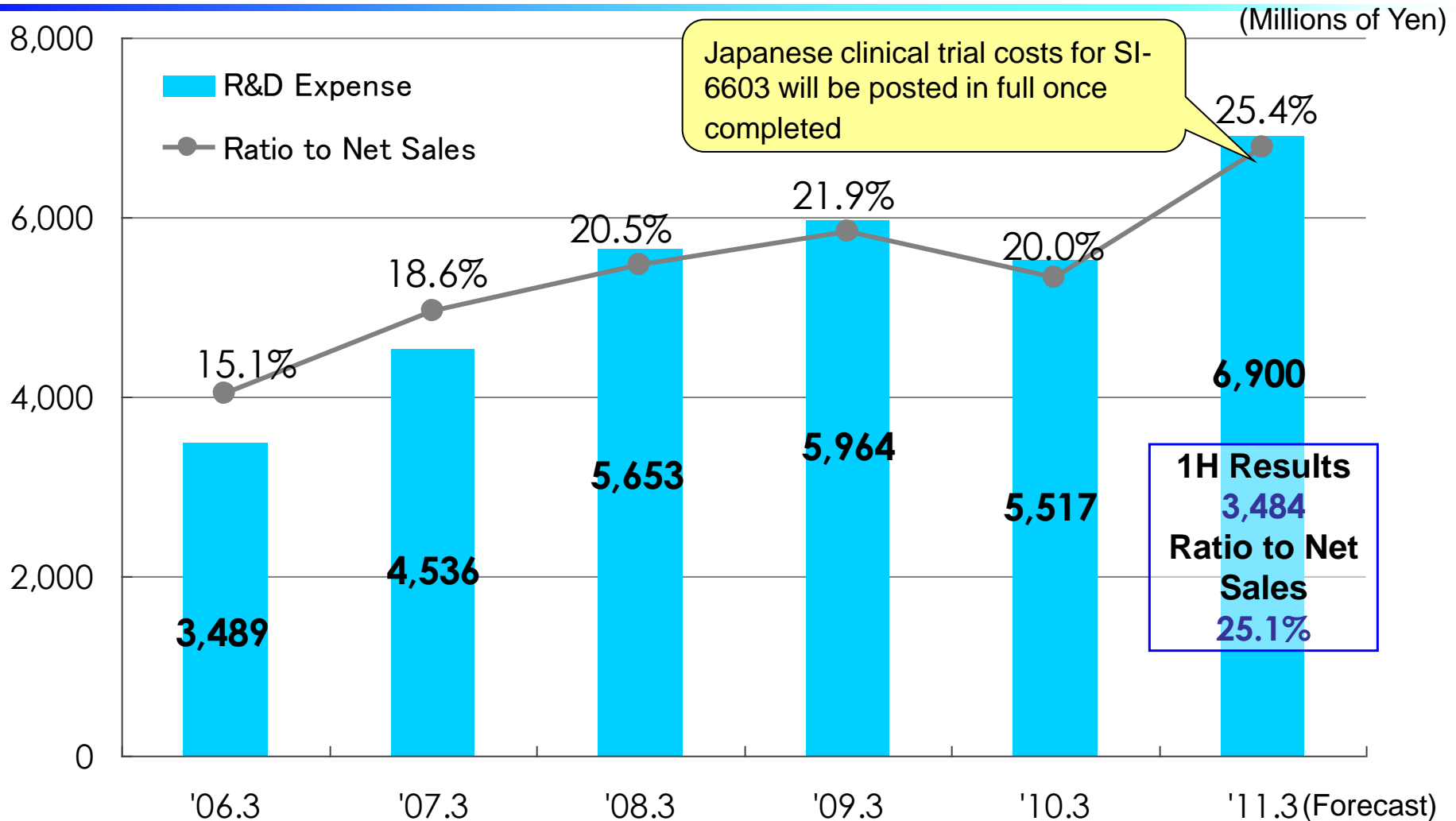
## Net income: ¥2,700 million (-¥300 mil./-10.0%)

- Increase in non-operating expenses: Higher currency exchange losses caused by high yen, relating to valuation of foreign currency-denominated assets and other factors

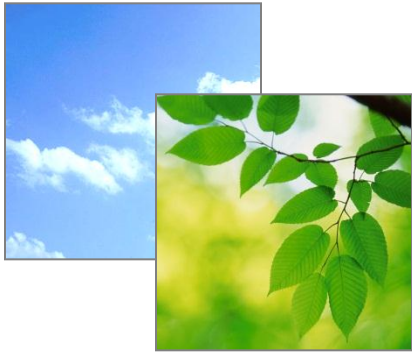
◆ **Point:** Net sales forecast lowered because of reduced sales of fine chemicals and the impact of the high yen. Income forecast also lowered, reflecting increases in R&D expenses and currency exchange losses.



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



◆ **Point:** R&D expenses will be increased due to the posting in full cost for Japanese clinical trails of SI-6603 once completed

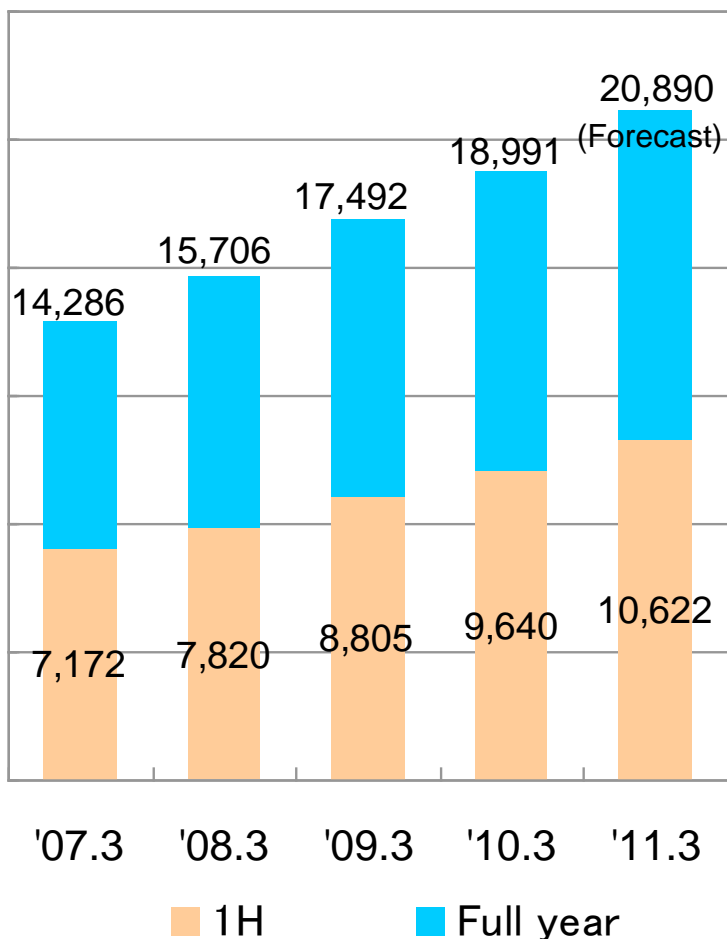


## Sales of ARTZ and OPEGAN

# Domestic Sales of ARTZ (Unit Deliveries to Medical Institutions)

## ARTZ Deliveries to Medical Institutions

(Thousand units)



### ■ 1H Results (year-on-year)

[Market] +7.5%

- Growth of aged population
- Continuation of Seikagaku's disease awareness campaign

[ARTZ] +10.2%

- Enhanced brand potential as pioneering product
- Introduction of a plastic syringe products
- Cut in NHI reimbursement price (-7.7%) offset by strong volume growth in sales, resulting in healthy sales for Seikagaku

Higher market share  
53.7%: +1.3pt (y-o-y)

### ■ Full-year Forecasts for FY2010 (year-on-year)

[Market] +8.5%

[ARTZ] +10.0%

Increase in consultation rate (thanks to continuing disease awareness campaign),

Promote initiatives to expand ARTZ prescription rate

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

# Initiatives to Expand the Total Market and ARTZ Prescriptions

## Expanding ARTZ in prescriptions

- **Introduction of a new plastic syringe in June 2010**
- Approaches to medical institutions through use of disease awareness campaign pamphlets, etc
- Expanding marketing to physicians in fields other than orthopedic surgery



Plastic syringes used for ARTZ Dispo

## Market expansion by disease awareness campaign

露木茂さん、セーフでした。あなたのひざは大丈夫？

ちょっとしたひざの違和感や痛み、実は病気かもしれません。早めに整形外科医に相談を。

お医者さんと治そう

### 変形性ひざ関節症

生化学工業株式会社

Advertisement placed in morning editions of Yomiuri Shimbun (national daily newspaper) in September 2010

ひざイキイキ あなたの「歩く」喜びを応援します。

あなたの街のお医者さん

第1回 痛みをとったらトレーニングで進行を予防 一人ひとりのひざの症状とニーズに合った治療を

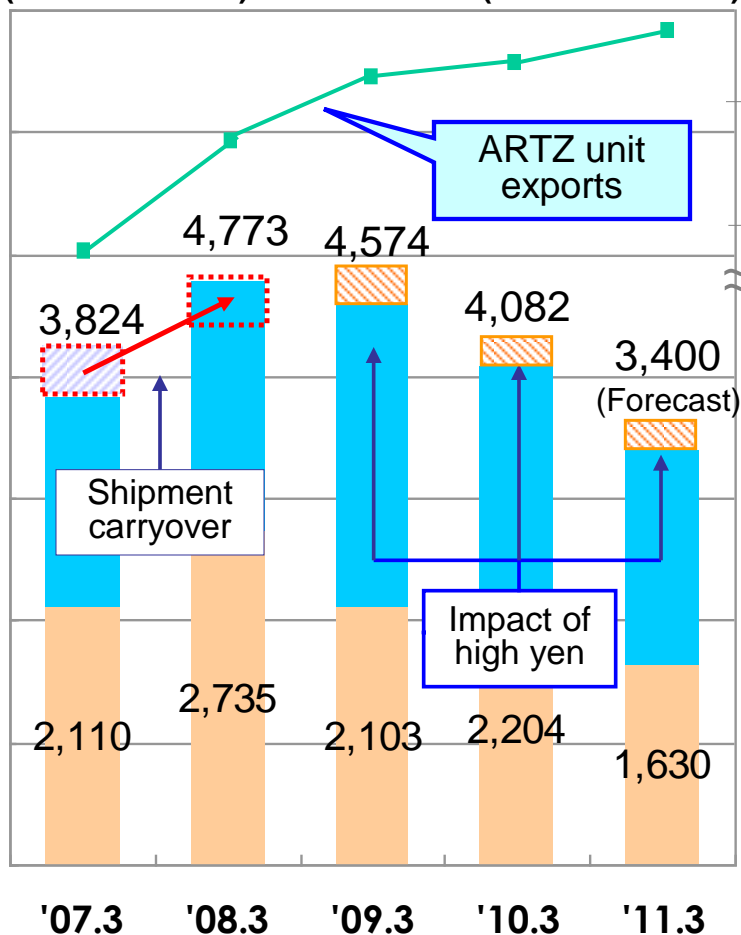
生化学工業株式会社

New content “Doctors in your community” added to disease awareness website “Hiza Ikiiki”.

# Overseas Pharmaceuticals Sales (Value Basis)

## Overseas Pharmaceuticals Sales

(Millions of Yen) (Thousand units)



■ 1H ■ Full year

■ **1H Results : -26.0%\* (year-on-year)**  
[U.S.]

**Local sales: -6.7%**

Volume decline from non-endorsement for reimbursement by some private health insurers etc

Sales unit prices bottomed out

**Seikagaku export sales: -20.7%**

Negative factors include local inventory build-up at end of the previous fiscal year, and impact of high yen (approx. -7%)

**[Other markets]**

**Seikagaku export sales: +6.4%**

Exports boosted by higher local sales in China (approx. 20% up) and shipment carryover from the previous fiscal year

■ **Full-year Forecasts for FY2010: -16.7%\* (year-on-year)**  
[U.S.]

**Local sales:** Aiming to reduce size of downturn by using insurance reimbursement support system to strengthen sales promotion activities

**Seikagaku export sales: -18.3%**

Lower because of reduced shipment volumes and high yen

**[Other markets] +16.7%**

Growth in local sales in China

Shipments to Italy concentrated into 3Q and later

\* Includes negative impact of one-time overseas royalty revenue received in 2009/1H.

# Sales Initiatives in U.S and China Markets

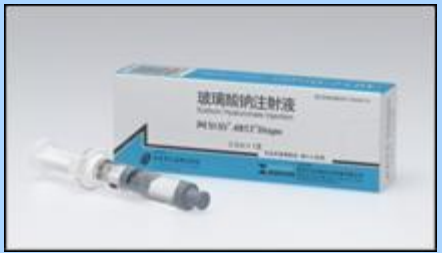
## United States: SUPARTZ



“My Knee and Me” website

- Introduction of “**SUPARTZ Direct**” (insurance reimbursement support system)  
Increased sales to Specialty Pharmacies (major pharmaceutical wholesalers)  
Relatively high sales units price, no influence from non- endorsement for reimbursement  
Unit price bottomed out
- “**My Knee and Me**” launched by Smith & Nephew (disease awareness site)  
For the improvement of the SUPARTZ recognition and patient follow-up

## China: 阿尔治 (ARTZ)

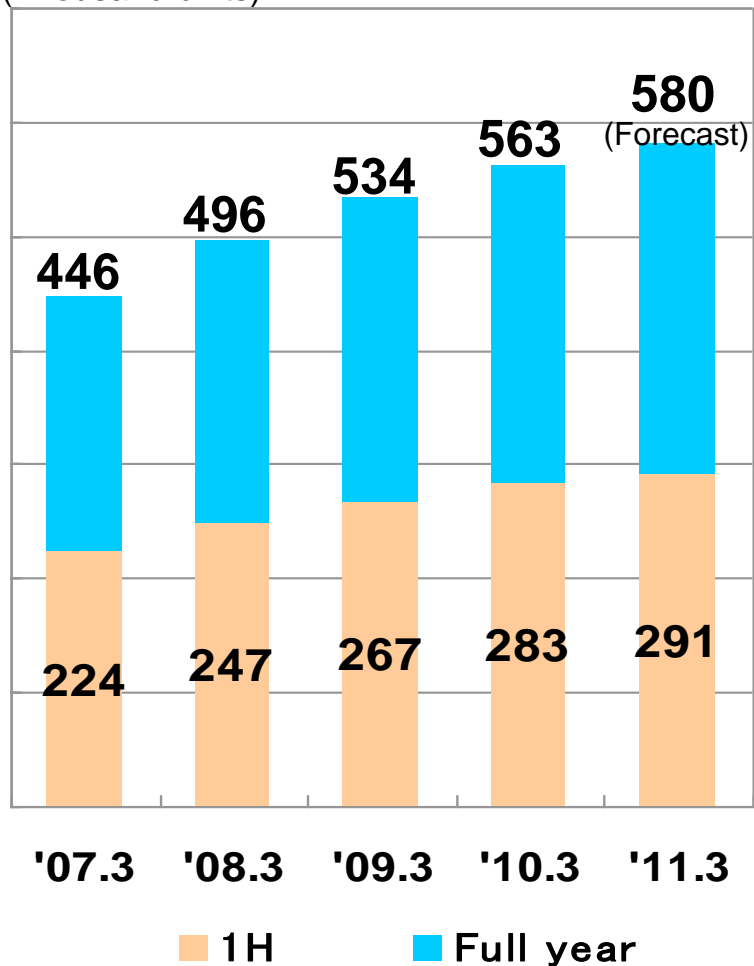


- Promoting awareness of knee osteoarthritis and develop the ARTZ brand strategy, especially at large hospitals in major cities
- Prevailing injection technique to doctor with no experience to use hyaluronic acid preparations

# Sales of OPEGAN (Unit Deliveries to Medical Institutions)

## OPEGAN deliveries to medical institutions

(Thousand units)



### ■ 1H Results (year-on-year)

[Market] +2.5%

Increase in cataract surgery resulting from growth of aged population

[OPEGAN] +2.7%

Continuation of sales promotion activities with high customer satisfaction

### ■ Full-year Forecasts for FY2010 (year-on-year)

[Market] +2.5%

-Market growth similar to previous year's result forecasted

[OPEGAN] +3.0%

- A new competing product expected to have minimal impact on sales, forecast increased (from +1.0% to +3.0%)

- Aiming to maintain sales growth rate higher than market growth

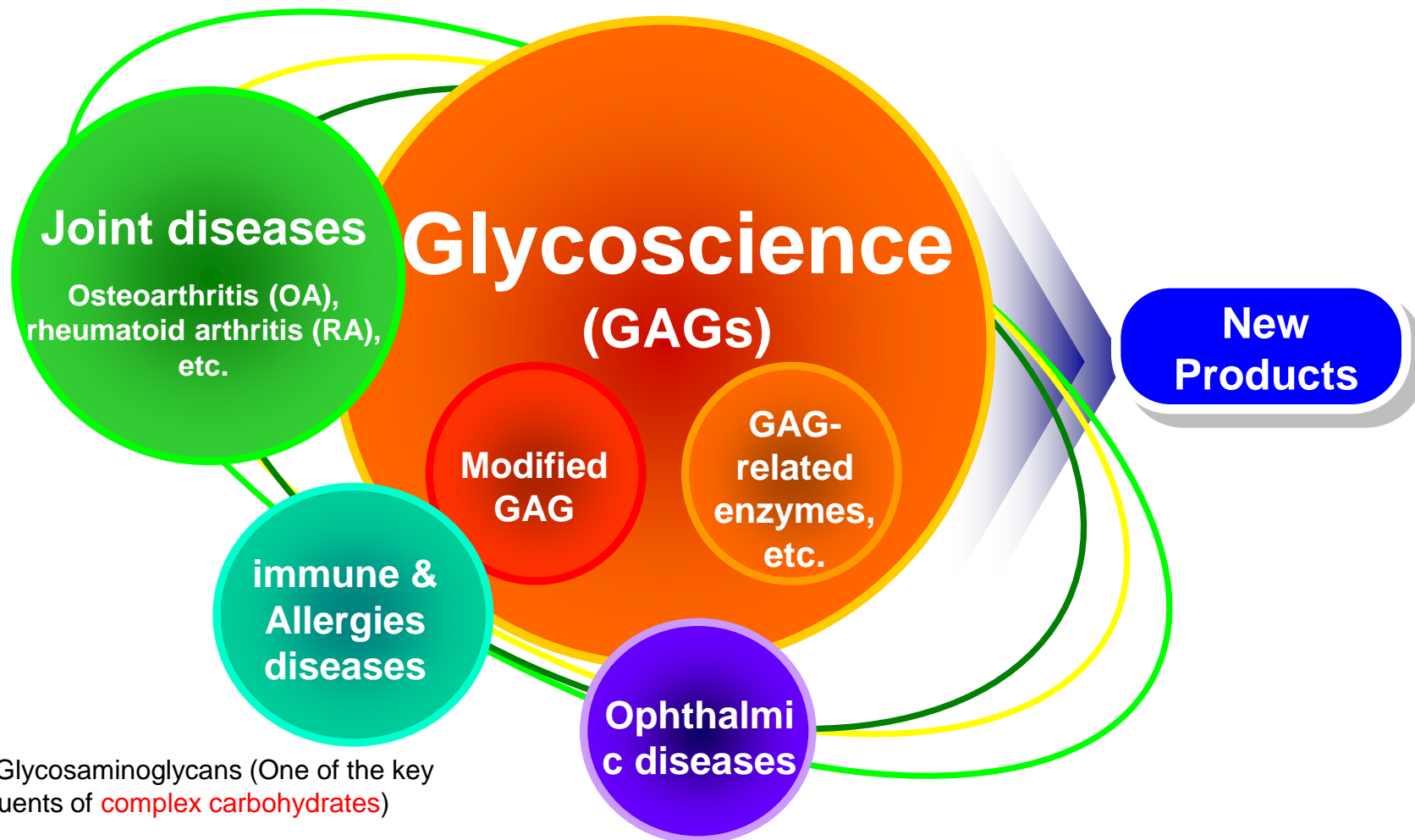
OPEGAN: A cataract surgery aid with hyaluronic acid as its main ingredient



## Current Status of the R&D Activities



# Basic Policy on Research and Development



GAG: Glycosaminoglycans (One of the key constituents of **complex carbohydrates**)

◆ **Point:** Our strategy is to focus on our specialist field of glycoscience, and to bring new products to market early and continuously through a balanced combination of in-house development and in-licensing.

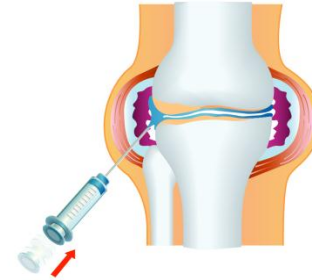


# Pipeline List

Development code/ Product name etc.	Lead Indication	Target Market	Pre-clinical	P I	P II	P III	Applica- tion	App- roval
<b>Gel-200</b> Cross-linked hyaluronate hydrogel	Knee osteoarthritis	<b>U.S.</b>					●	
<b>SI-602</b> Additional indication for SUPARTZ (U.S.)	Shoulder osteoarthritis	<b>U.S.</b>					●	
<b>SI-6603</b> Chondroitinase ABC	Lumbar disc herniation	<b>Japan</b>			●		P II / III	
		<b>U.S.</b>			●			
<b>SI-615</b> Adenosine A3 receptor agonist	Rheumatoid arthritis	<b>Japan</b>		●				
<b>SI-636</b> Anti-VAP-1 antibodies	Rheumatoid arthritis, Psoriasis, Inflammatory bowel disease	<b>Japan</b>	●					
	Ophthalmic products		●					
	Arthritic disorder products		●					

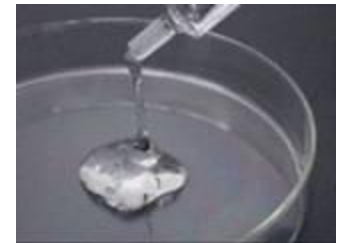
# Gel-200

- ◆ Substance : Cross-linked hyaluranate hydrogel
- ◆ Indications: Knee osteoarthritis
- ◆ Administration method: Injection into knee joint (single injection)



An inflamed knee joint

Because of its high viscoelasticity, Gel-200 remains within the joint cavity for long term



## [Results of approval application]

Results of FDA review received in January 2010  
Not approvable at present

## [Response]

Amendment to PMA submitted in June 2010, discussions with FDA ongoing

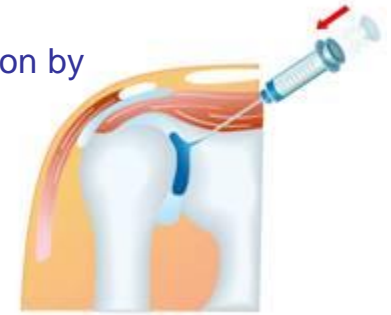
### ◆ Features

- Intra-articular injection formula with cross-linked hyaluranate hydrogel as its main constituent, developed based on original Seikagaku cross-linking technology.
- Hyaluronic acid improves lubrication in knee joints by coating the cartilage.
- Because Gel-200 is retained long term within knee joint cavity, long-term pain relief can be achieved with a single injection.

# SI-602

- ◆ Substance : Sodium hyaluronate
- ◆ Indications: Shoulder osteoarthritis  
(additional indication for SUPARTZ in the United States)
- ◆ Administration method: Injection into shoulder joint

SI-602 improves lubrication by coating the cartilage.



An inflamed shoulder

## [Results of Phase III trials]

- Statistically significant reduction in pain compared with placebo group
- No safety issues

## [Current stage]

- PMA application filed with FDA in September 2009, currently under review



## ◆ Features

- Cartilage coated with hyaluronic acid to improve lubrication in shoulder joint cavity
- Jointly developed with sales partner, Smith & Nephew
- The first hyaluronic acid product used to treat shoulder osteoarthritis in the United States (if approved)
- Periarthritis of shoulder already included in indications for ARTZ in Japan

# SI-6603

- ◆ Substance name: Chondroitinase ABC
- ◆ Indication: Lumbar disc herniation
- ◆ Method of use: Injection into lumbar disc (under X-ray observation)

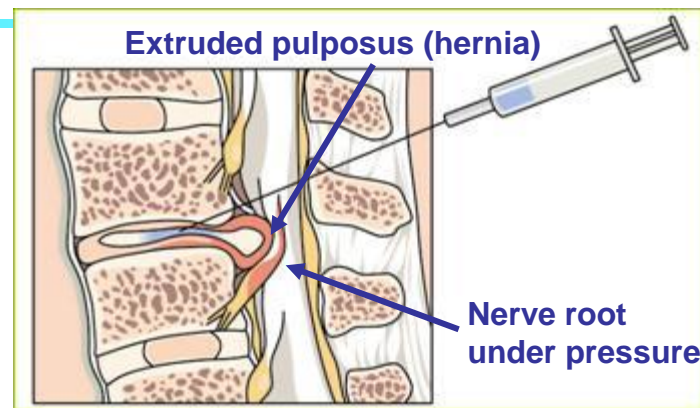
## [Current stage]

- Japan: PII/PIII ⇒

Progress monitoring completed in August 2010, final analysis results expected by December, 2010



- United States: PII ⇒ Patient enrollment in progress

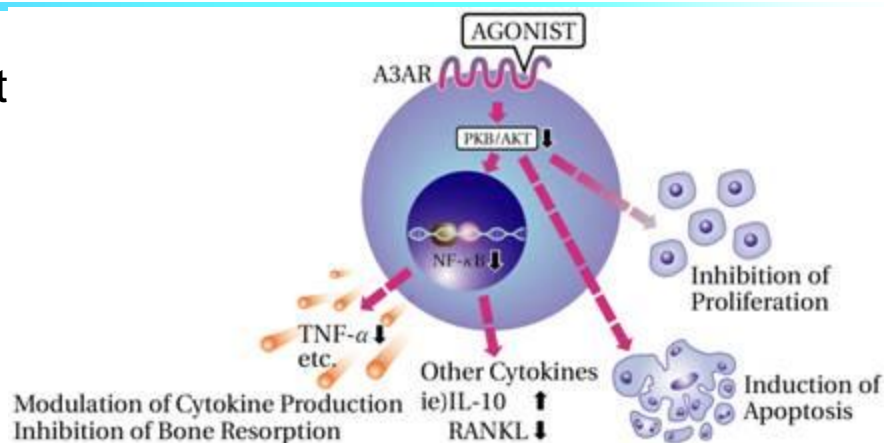


## ◆ Features

- 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
- Single-injection treatment with SI-6603 expected to become an alternative to surgery
- No breakdown of proteins, so no effect on other tissues (blood vessels, nerves, etc.)

# SI-615

- ◆ Substance: Adenosine A3 receptor agonist
- ◆ Indications: Rheumatoid arthritis
- ◆ Administration method: Oral



## [Current stage]

- Phase I in Japan
- Phase II in Europe, etc. implemented by CanFite

⇒ Seikagaku will reassess its future development policy based on progress with the PIIb monotherapy trial that is currently being planned by the licensor, CanFite.

### ◆ Features

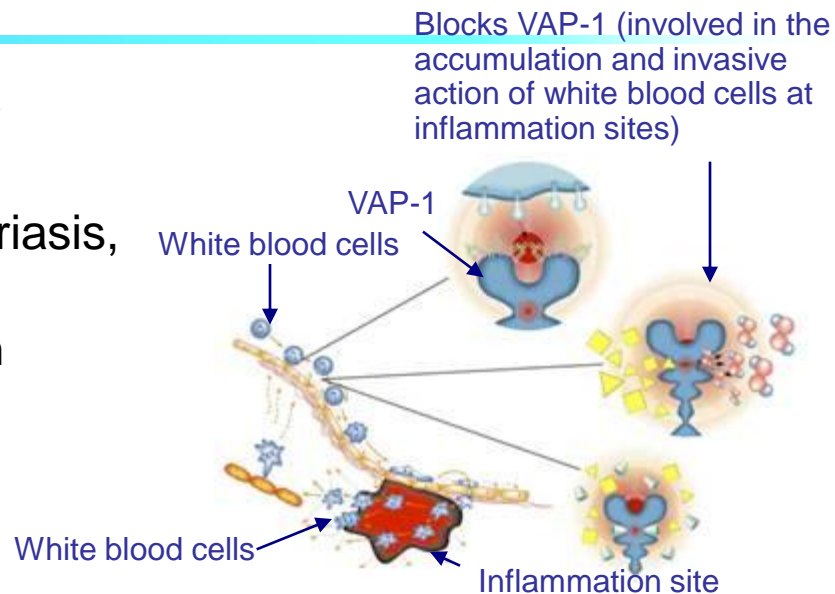
- Licensed in from CanFite BioPharma
- Selective action against adenosine A3 receptors, which are expressed prolifically at inflammation sites
- Thought to suppress intracellular signal transduction involving pathogenesis of inflammation and the production of proinflammatory cytokine.

# SI-636

- ◆ Substance: Anti-VAP-1 monoclonal antibody
- ◆ Indications: Inflammatory diseases  
(Target diseases: Rheumatoid arthritis, psoriasis, inflammatory bowel disease)
- ◆ Administration method: Intravenous injection

## [Current stage]

- Pre-clinical stage in Japan
- PI (Europe), implemented by BioTie
  - ⇒ - The licensor, BioTie, has completed PI repeat-dose trial for joint rheumatism, confirming tolerability and the absence of serious side-effects.
  - Seikagaku will assess its future development policy based on progress made with trials conducted by BioTie.



## ◆ Features

- Licensed in from BioTie Therapies
- Expected to reduce inflammation by blocking the adhesion molecule VAP-1, which is involved in white cell accumulation and invasion at inflammation sites
- Extremely novel substance that acts on an adhesion molecule that controls the action of white blood cells, in contrast with traditional anti-inflammatory drugs that curb the production and action of inflammatory substances



## Improvement Measures for Shareholder's value



# Basic Policy on Profit Distribution

## ◆ Dividends

A performance-based dividend policy emphasizing the dividend payout ratio is in place, on a ¥20 per share annual base. We will aim for further improvements, while maintaining a consolidated base dividend payout ratio of 30%.

## ◆ 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

	FY 2006	FY2007	FY2008	FY2009	FY2010 (Forecast)
Net Income per Share	¥60.93	¥73.67	¥55.68	¥62.94	¥47.53
Annual Total Dividend	¥25.00	* ¥30.00	¥25.00	¥25.00	¥25.00
Dividend Payout Ratio	41.0%	40.7%	44.9%	39.7%	52.6%

\* The dividend for FY2007 includes a ¥5 commemorative dividend to mark the Company's 60th anniversary.

# Ten-Year Vision and Mid-term Plan

## The Seikagaku Corporation Ten-Year Vision

### “Global Category Pharma”

- Converge major R&D resources on Glycoscience
- Develop internationally competitive products

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

### Mid-term Plan FY2009-2011

Foster the basic corporate strength and develop the core systems essential to realization of the Ten-Year Vision

Theme

**G·P·S**(Global, Powerful, Sustainable)

Accurately assess the current position and move toward future through powerful and sustainable action in the right direction

# Financial Target of Mid-term Plan

- Depreciation of new facility beginning in FY2008 (A peak in FY2009)
- R&D expenses ratio to sales:20% or over invest ¥6.0bil - ¥6.3bil annually
- Enforced drug price revision in FY2010

**FY2011**  
**Net Sales**  
**¥30.5bil**  
**Op. Income**  
**¥6.0bil**

**FY2008**  
**Net Sales: ¥27.2bil**  
**Op. Income: ¥4.7bil**

## Sales growth in Japan (ARTZ & OPEGAN)

Sales increase in ROW (China etc.)

Sales increase in fine chemicals

Approval of additional indication (SUPARTZ)

Gel-200 launch in U.S. market

## Toward Long-term Growth

- Further expansion in Japan
- SI-6603 launch in Japan/U.S.
- Growth of Gel-200
- Market development of ARTZ

## 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

# ◆ Changes to Sales Segment Reporting

As a result of changes to accounting standards, our results for the current quarter are based on two segments: pharmaceuticals and fine chemicals. The sales items included in each segment are as follows.

## 1) Pharmaceuticals

Domestic pharmaceuticals: Sales relating to pharmaceutical products business in the domestic market

Overseas pharmaceuticals: Sales relating to exports of pharmaceutical products business

## 2) Fine chemicals

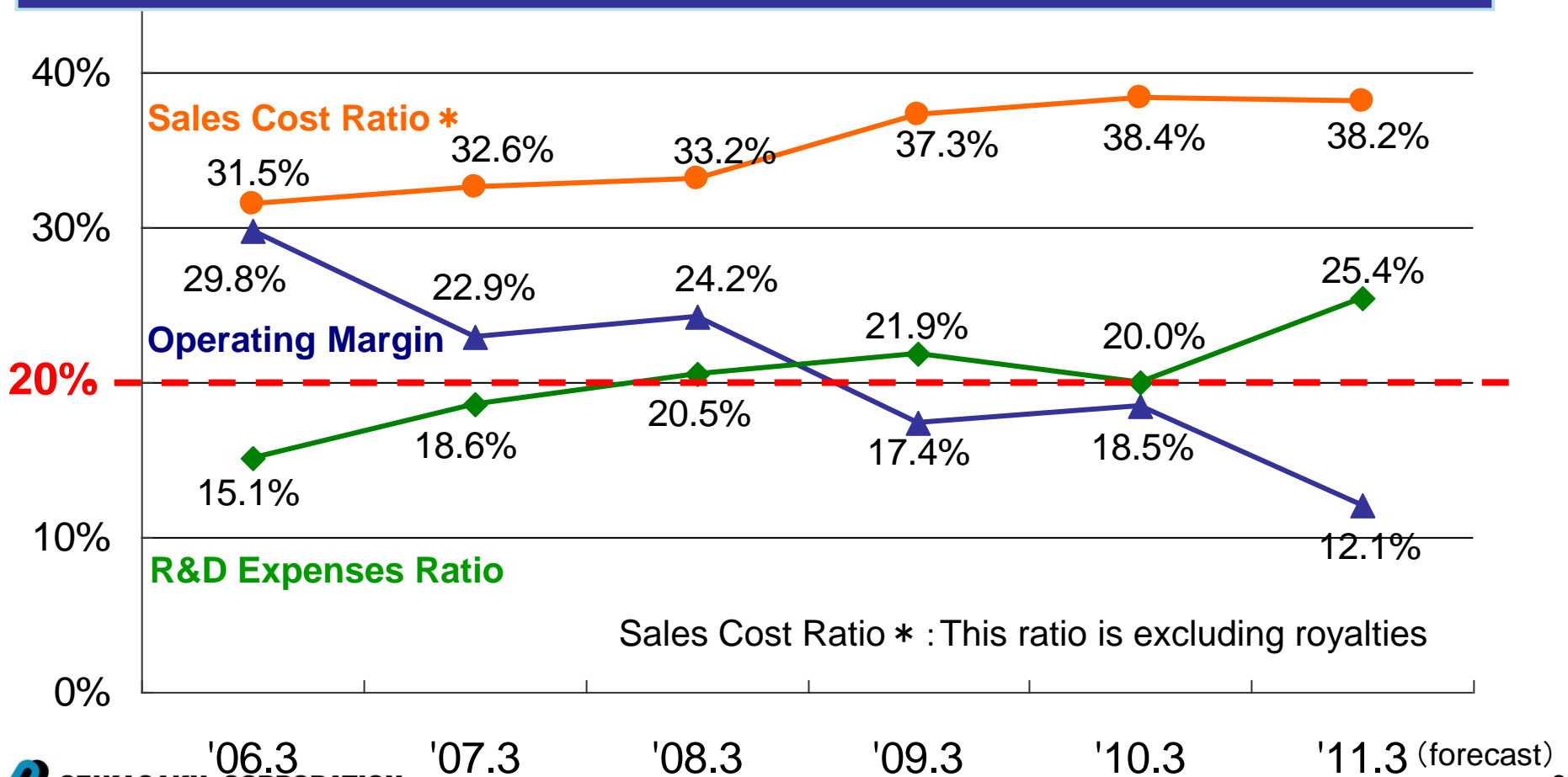
Reagents and diagnostics: Sales relating to reagents and diagnostics business

Bulk products: Sales relating to active pharmaceutical ingredients and the health food raw material business, etc.

To allow comparisons with the same period in the previous year, the results for that period were recalculated to reflect these changes.

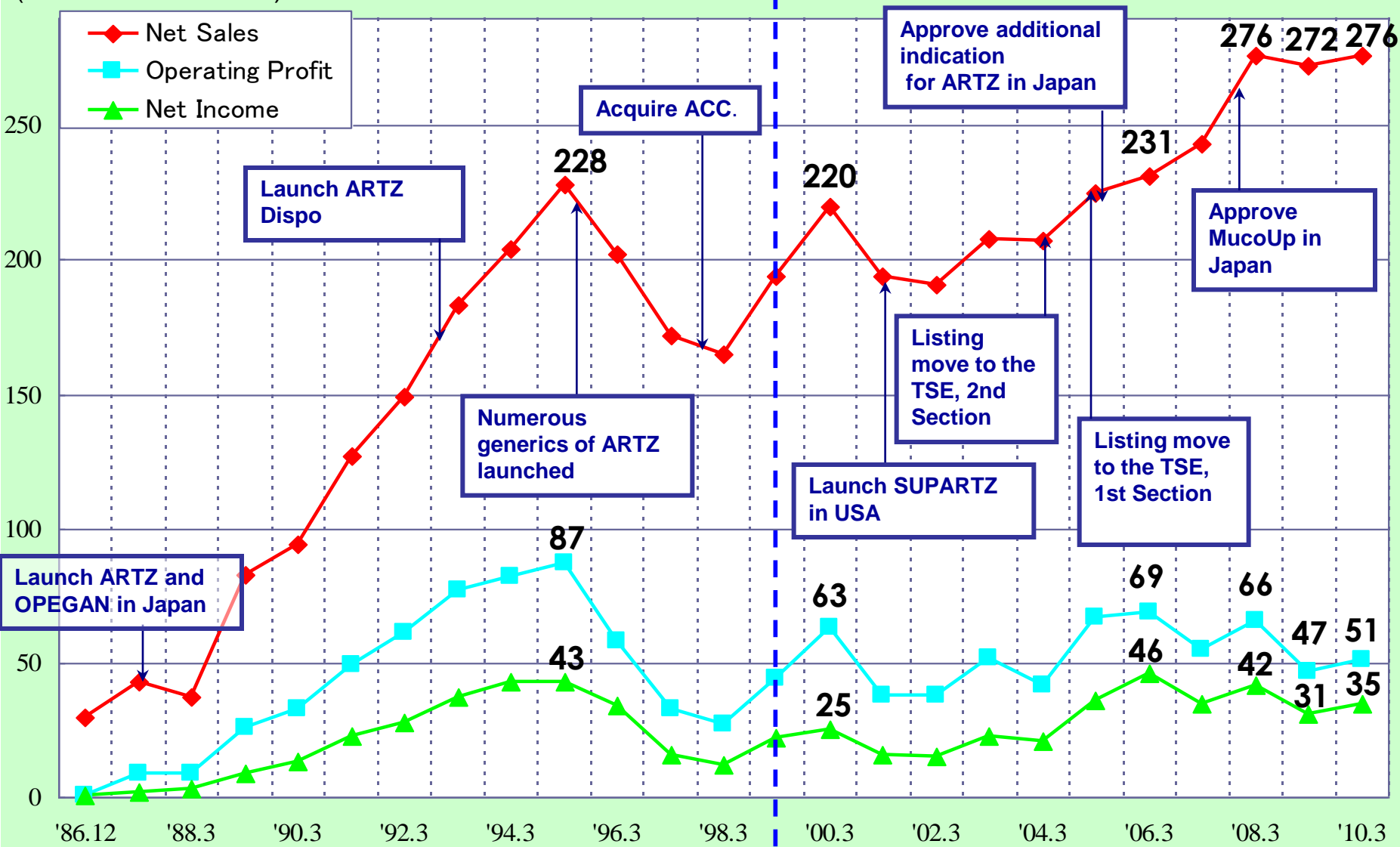
# Trend in Financial Index

◆ **Point:** Depreciation of the new ARTZ Dispo production building began in the year ended March 2009. Lump-sum posting of Japanese clinical trial costs for SI-6603 will be included in full in R&D expenses for the year ending March 2011.



# Business Progress & Highlights

(Hundred Million Yen)



⇒ Consolidated results from '99.3

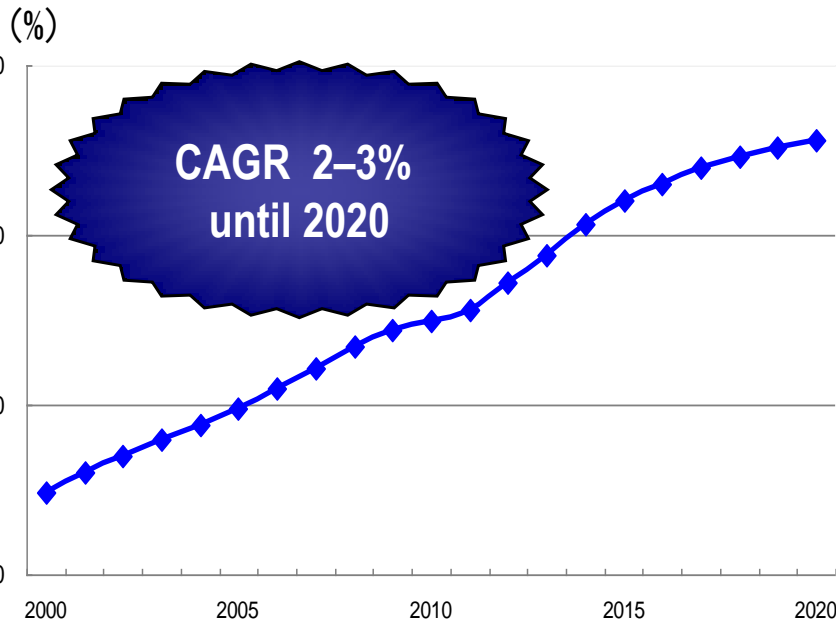


# Expanding Market of ARTZ in Japan

- Japanese knee osteoarthritis (OA) market continues to grow due to aging population
- There are 24 million latent patients with knee OA, whereas patients under treatment are 8.2 million (Survey conducted by the Tokyo University)

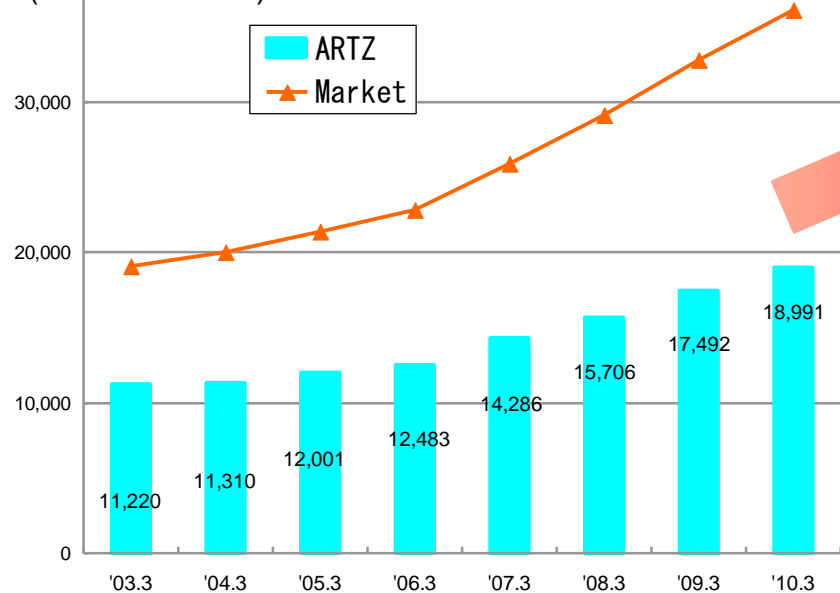
## ■ Growing Elderly Population (65 or over)

(Source: Ministry of Internal Affairs and Communications)



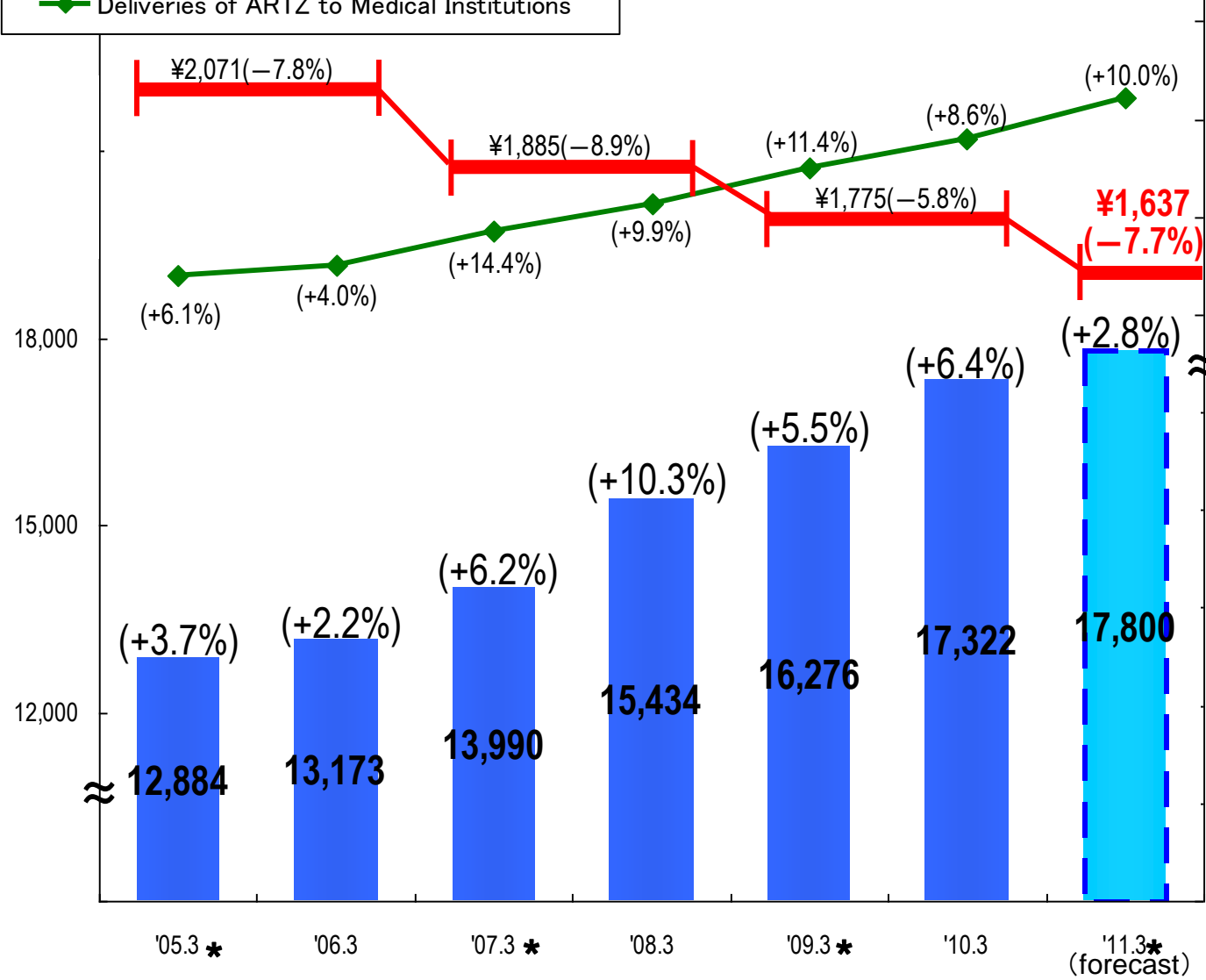
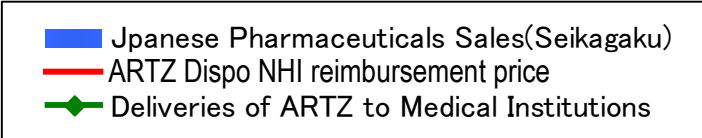
## ■ Deliveries of ARTZ to Medical Institutions (Japan)

(Thousand units)



# Trend in NHI Reimbursement Price and Our Domestic Pharmaceuticals Sales

NHI price cuts offset by increased volumes, allowing continued revenue growth



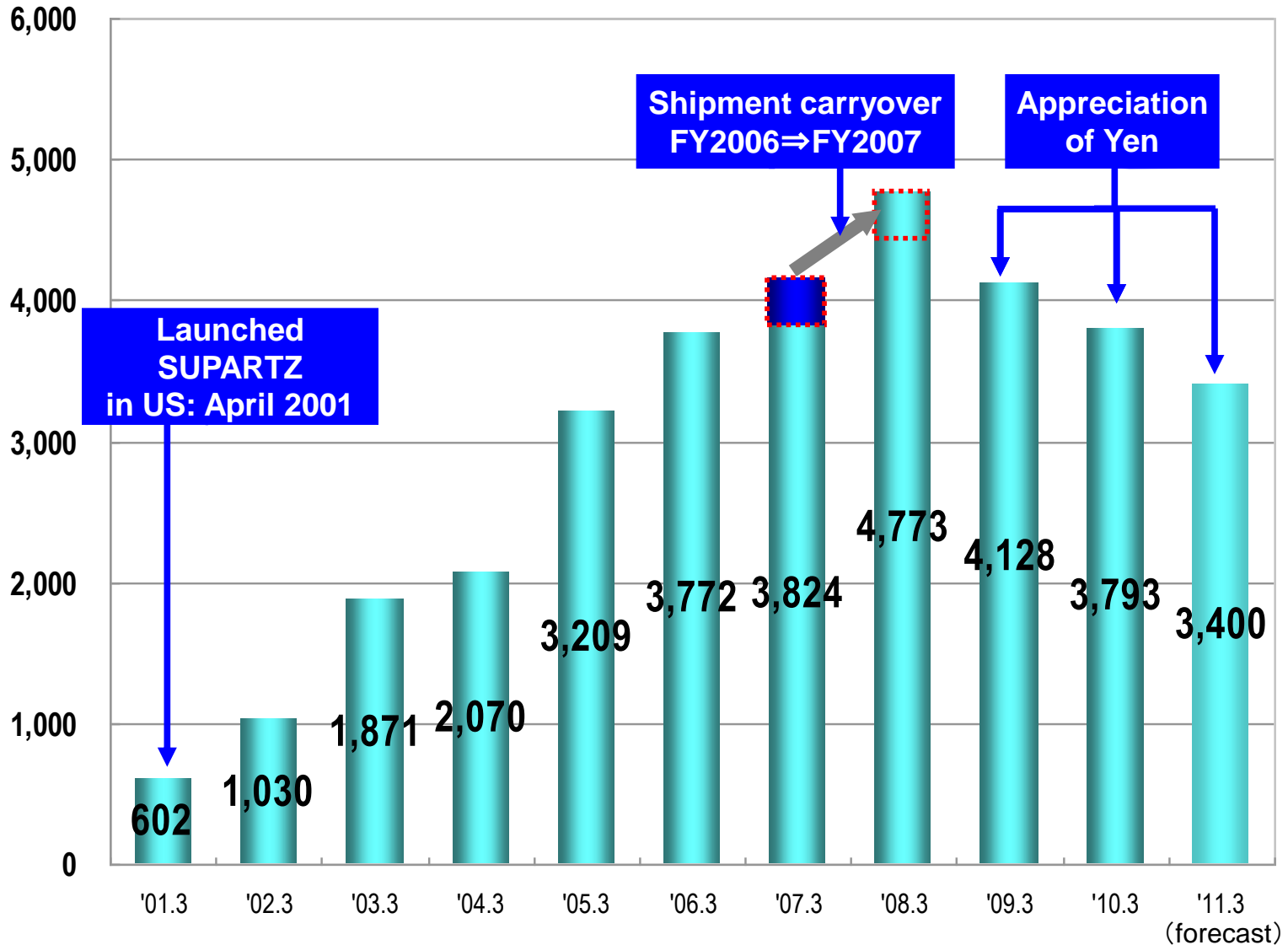
**NHI price revision in FY2010**

- Industry average: **-6.3%**
- Long-term listed items: **additional 2.2% cut**

\* National Health Insurance drug price revision

# Trend in Hyaluronic Acid Products in Overseas Market

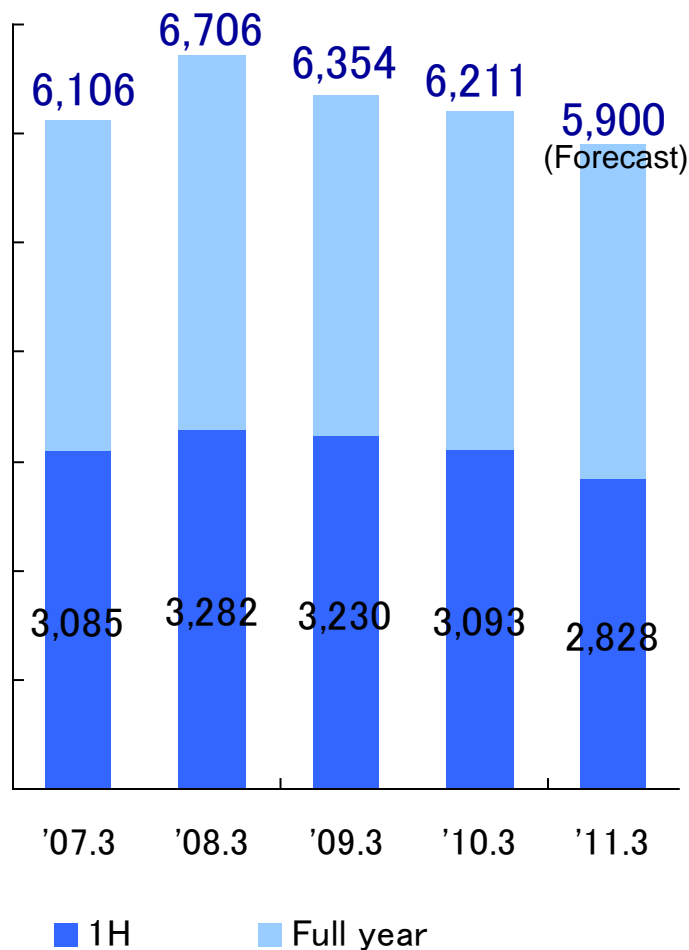
(Millions of Yen)



# Sales of Fine Chemicals (Value basis)

## Sales of fine chemicals

(Millions of Yen)



### ■ 1H Results -8.6% (year-on-year)

[Bulk Products] -28.6%

Lower sales due to postponement of hyaluronic acid shipment until 3Q or later

[Research Reagents & Diagnostics] -0.8%

Healthy growth at ACC, but domestic sales of original reagents fell

### ■ FY2010 Forecasts -5.0% (year-on-year)

[Bulk Products] +5.4%

Sales increase of hyaluronic acid because postponement of shipment will be resolved

[Research Reagents & Diagnostics] -8.7%

-Overseas sales of endotoxin-detecting reagents to be declined due to high yen

-Domestic sales of some reagents to be lower

## 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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