



*Glycoscience for Human Well-being*

# Financial Results for the Fiscal Year 2009

(April 1, 2009-March 31, 2010)



**SEIKAGAKU CORPORATION**



# Financial Results for FY2009

(Million of Yen)

	FY 2009 Results	FY 2008 Results	vs. Previous Year	Forecast 11/6 Announced	vs. Forecast
<b>Net Sales</b>	27,617	27,207	+409 (+1.5%)	27,800	-182 (-0.7%)
<b>Operating Income</b>	5,110	4,729	+381 (+8.1%)	4,700	+410 (+8.7%)
<b>Ordinary Income</b>	5,114	5,094	+20 (+0.4%)	4,700	+414 (+8.8%)
<b>Net Income</b>	3,575	3,175	+400 (+12.6%)	3,200	+375 (+11.7%)
<b>Net Income per Share</b>	¥62.94	¥55.68	+¥7.26	¥56.33	+¥6.61

Exchange Rate  
(1US\$)

¥92.86

¥100.54

¥91.00  
(2<sup>nd</sup> half forecast)



# Factors Influencing Business Results for FY2009

(year-on-year comparisons)

(Million of Yen)

**Net sales: ¥27,617 million (+409, +1.5%)**

**[Pharmaceuticals (+710)]**

Japan (+1,046): Continued growth in sales of ARTZ and OPEGAN

Overseas (-335)– U.S.: Sales down due to high yen, lower selling local prices, etc.

– China: Shipment carryover into the following year lowered sales.

Strong local sales.

**[Research Reagents & Diagnostics (-244)]**

Overseas sales reduced by high yen. Domestic sales higher

**[Bulk Products (+101)]** Increased sales of hyaluronic acid

**[Other Products (-157)]** Reduced transient royalty income

**Operating income: ¥5,110 million (+381,+8.1%)**

**[Cost of sales (+510)]** Volume growth in pharmaceutical sales in Japan,  
depreciation of No.4 Production Building, other factors

*Cost of sales ratio (excluding royalties): 38.4% (+1.1 points)*

**[SG&A expenses (-481)]**

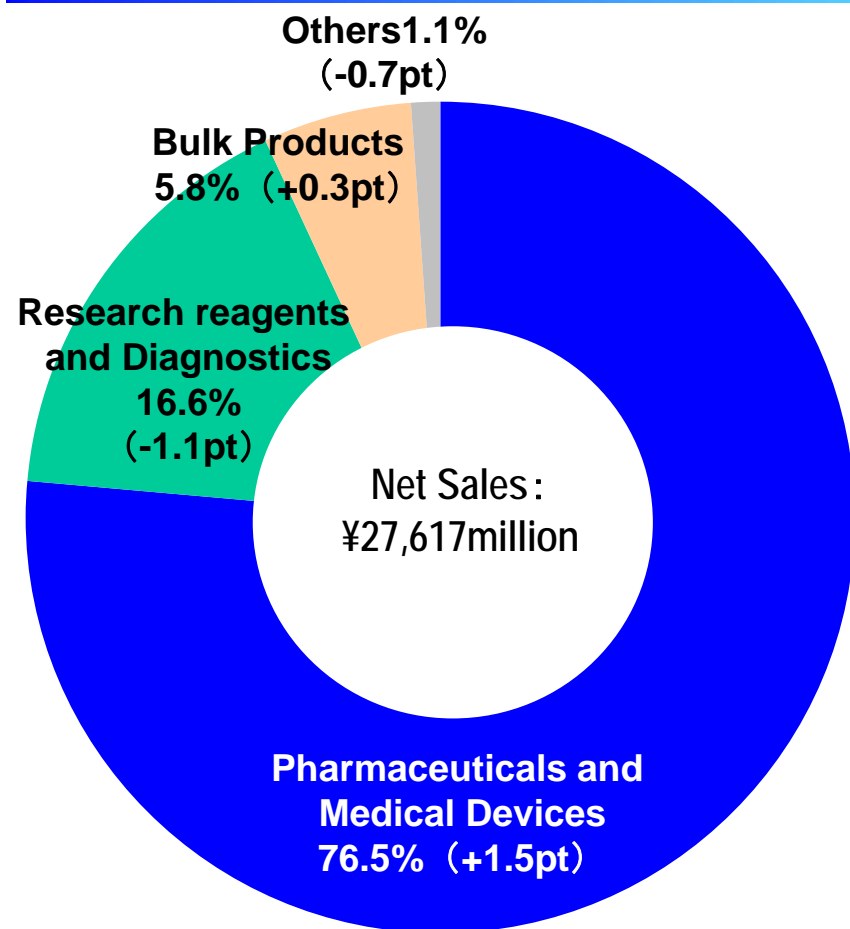
R&D expenses (-447): Cost of Gel-200 repeat-treatment trial included in 4Q FY2008

**Net income: ¥3,575 million (+400, +12.6%)**

**[Foreign exchange loss (+331)]** Increased exchange losses, including losses on  
redemption of foreign currency bonds

**[Extraordinary losses (-227)]** None in current year

# Net Sales by Business Segment



(Million of Yen)

Segment	Net Sales	vs. Previous Year	Change
Domestic Pharmaceuticals	17,322	+1,046	+6.4%
Overseas Pharmaceuticals	3,793	-335	-8.1%
Research reagents and Diagnostics	4,580	-244	-5.1%
Bulk Products	1,593	+101	+6.8%
Others	327	-157	-32.5%
Total	27,617	+409	+1.5%
(Overseas Sales)	6,654	-808	-10.8%



0%

25%

50%

75%

100%



# Factors for Changes from Forecasts of 11/6/2009

(Million of Yen)

**Net sales: ¥27,617 million (-182 / -0.7%)**

**[Positive Factors]**

- **Research reagents & diagnostics: Upward momentum from sales recovery in U.S.**

**[Negative Factors]**

- **Domestic pharmaceuticals: Downward trend in 4Q as medical institutions contain inventories in anticipation of drug price revision**
- **Overseas pharmaceuticals: Decline resulting from some ARTZ shipments to China carrying over into the following fiscal year**

**Operating income: ¥5,110 million (+410 / +8.7%)**

**Reduction in SG&A expenses**

**Reductions in R&D expenses and selling expenses, etc.**

**(R&D expenses -282: forecast 5,800 ⇒ actual 5,517)**

**Net income: ¥3,575 million (+375/ +11.7%)**

**Increase in income taxes**

**Due to higher pre-tax income**

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

(Million of Yen)

	Forecast for FY2010	FY2009	vs. Previous Year
<b>Net Sales</b>	27,800	27,617	+182 (+0.7%)
<b>Operating Income</b>	3,900	5,110	-1,210 (-23.7%)
<b>Ordinary Income</b>	4,100	5,114	-1,014 (-19.8%)
<b>Net Income</b>	3,000	3,575	-575 (-16.1%)
<b>Net Income per Share</b>	¥52.81	¥62.94	-¥10.13

Exchange Rate  
(1US\$)

¥92.00  
(Forecast)

¥92.86



## Factors Influencing FY2010 Forecasts (year-on-year comparisons)

(Million of Yen)

**Net sales: ¥27,800 million (-182 / -0.7%)**

**[Pharmaceuticals (+283)]**

Japan (+477): ARTZ sales growth despite price cut

Overseas (-193) – U.S.: Local sales volumes and prices lower because of tighter insurance reimbursement criteria

– China: Continued strong growth in local sales

**[Research Reagents & Diagnostics (+19)]**

Peaking of impacts from high yen and stagnant U.S. economy

**[Bulk Products (+106)]** Increased sales of hyaluronic acid

**[Others (-227)]** Reduced royalty income

**Operating income: ¥3,900 million (-1,210 / -23.7%)**

**[Cost of sales]**

Effect of drug price cuts offset by increase in production volume and lower depreciation on No. 4 Production Building

*Cost of sales ratio (excluding royalties): 38.3% (-0.1pt)*

**[SGA expenses]**

R&D expenses (+1,082): Cost of clinical trial in Japan for SI-6603

FY2009 actual: 5,517 ⇒ FY2010 forecast: 6,600

Also, increases in selling expenses, etc.

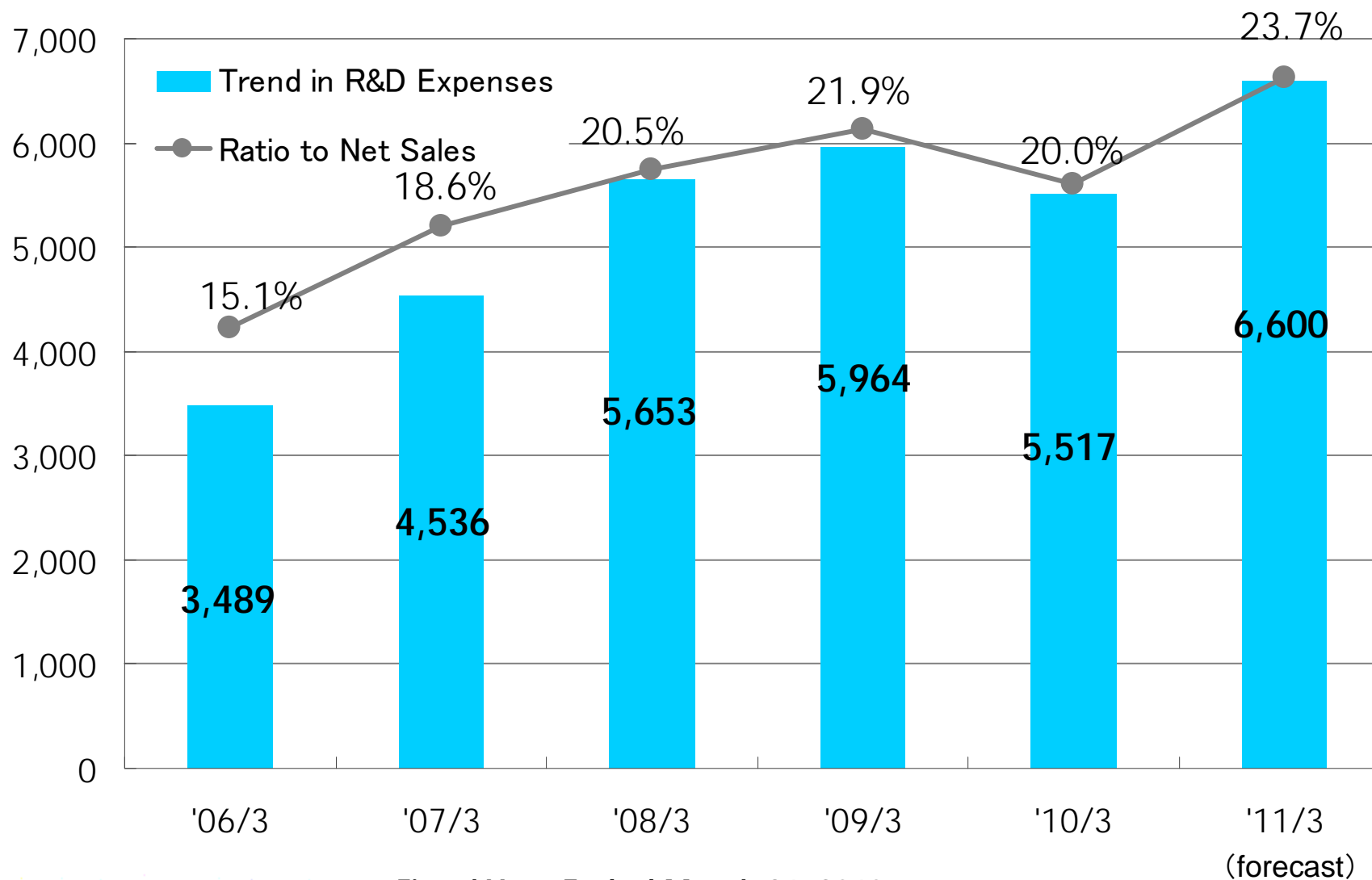
**Net income: ¥3,000 million (-575 / -16.1%)**

**Reduction in non-operating expenses:** Lower exchange losses

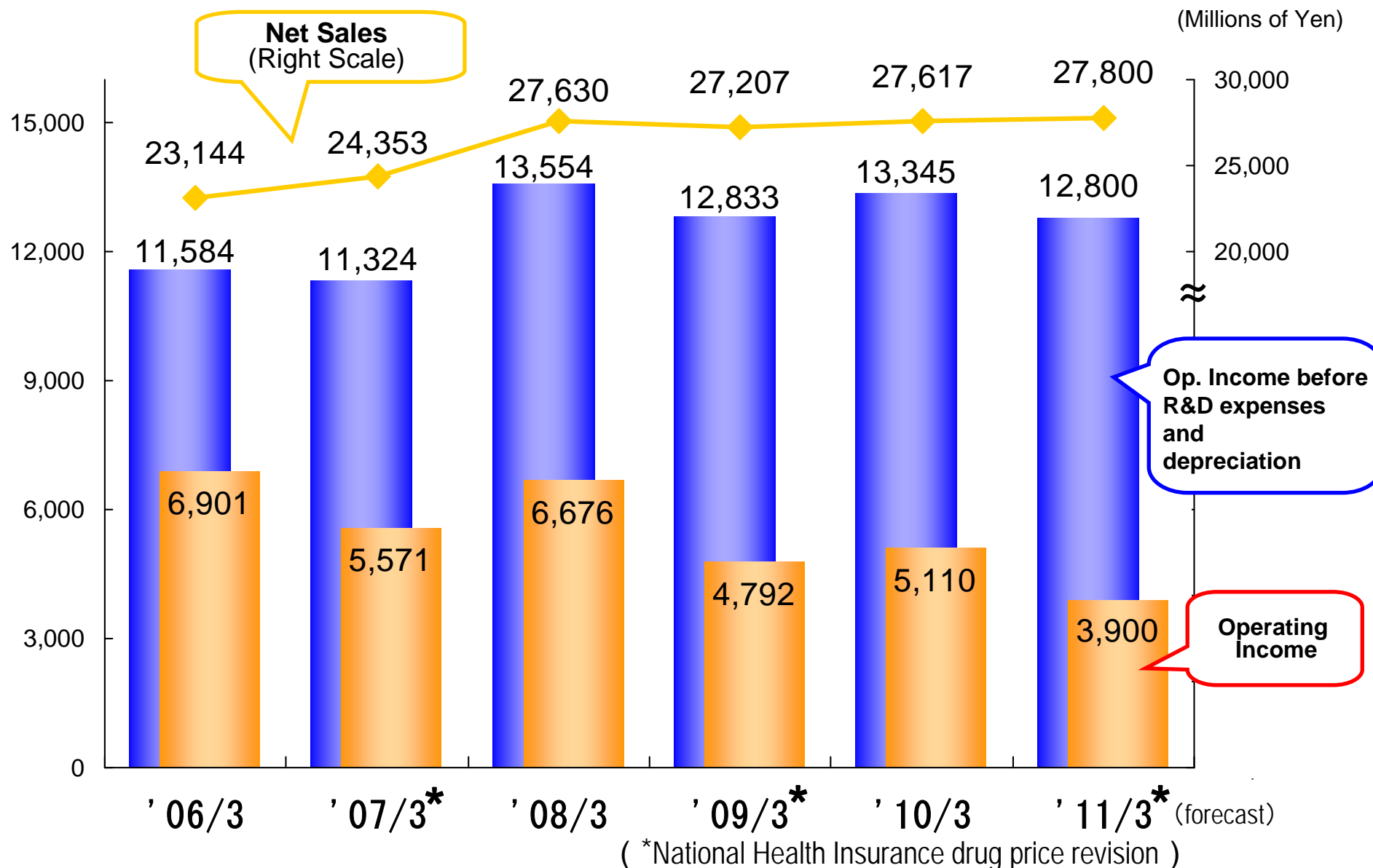
**Reduction in income taxes:** Lower pre-tax income

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

(Million of Yen)



# Financial Highlights

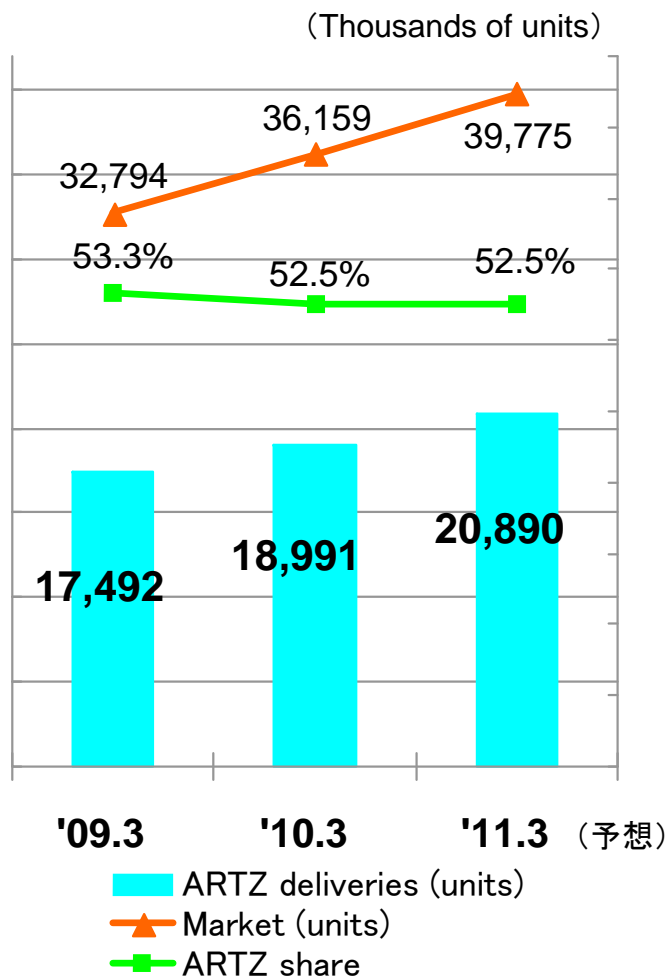


# **Sales of Core Products**



# Deliveries of ARTZ® to Medical Institutions in Japan

## ARTZ® (domestic)



(Unit deliveries to medical institutions, year-on-year change)

### ■ Results for FY2009

**<Market> +10.3%**

- Growing population of aged people
- Continuing campaign to raise public awareness of diseases ⇒ Discovery of latent patients

**<ARTZ®> +8.6%**

- Market growth reflected in volume increase in ARTZ® sales

### ■ Forecasts for FY2010

**<Market> +10%**

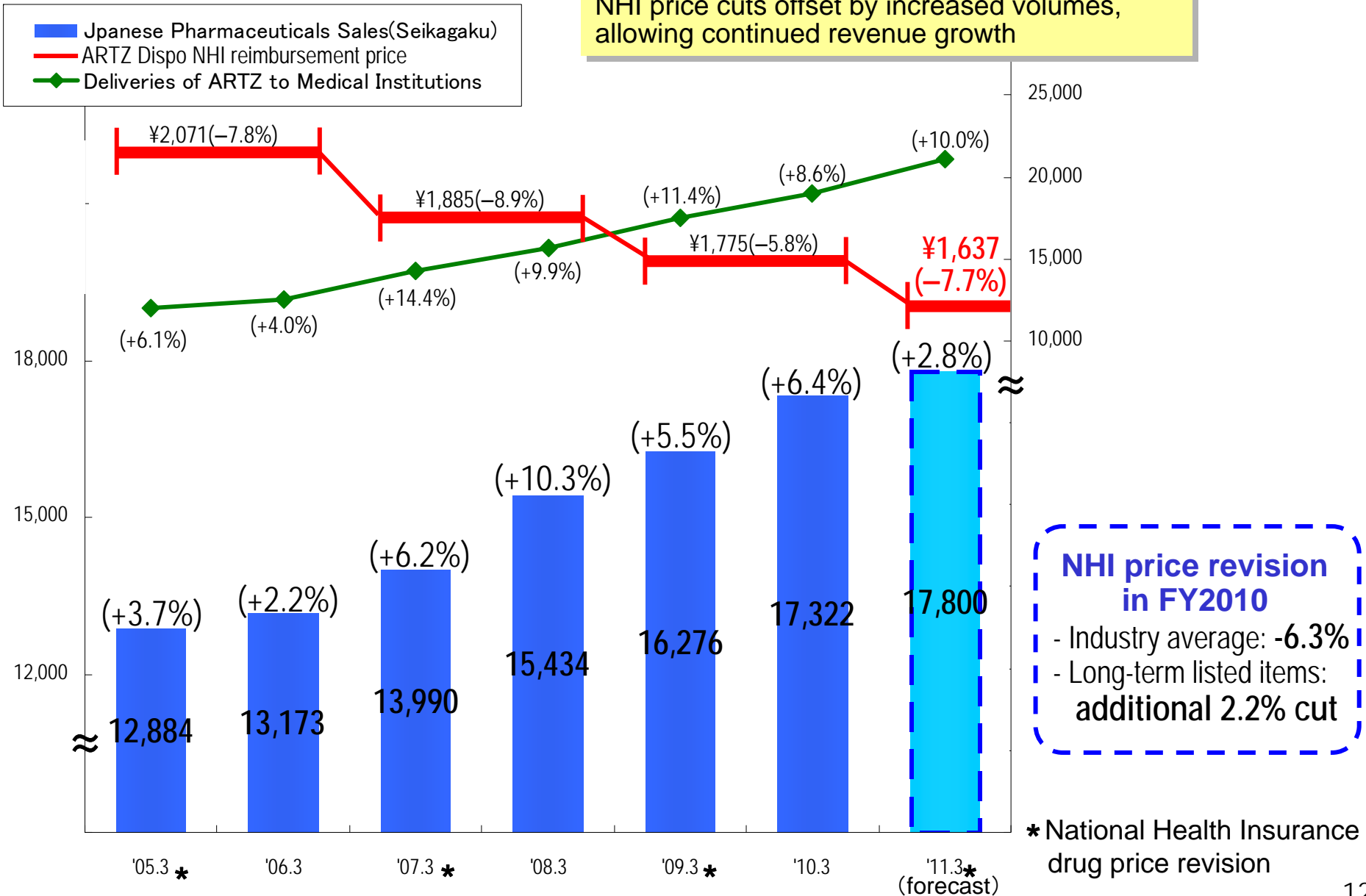
- Continued steady expansion

**<ARTZ®> +10%**

- Promoting measures to leverage increased patient visits (from public awareness campaign) into increased prescriptions for ARTZ®

# Trend in NHI Reimbursement Price and Our Domestic Pharmaceuticals Sales

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



# Initiatives to Expand ARTZ Market and Prescription Rate

## Market expansion through public awareness campaign



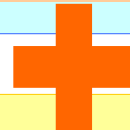
Hiza Iki-Iki (healthy knee) website (<http://www.ehiza.jp/>) launched in March 2010



TV special on knee pain in March 2010



Ads in national morning edition of Yomiuri Shinbun (September 2009)



## Initiatives to increase the prescription of ARTZ

- Using campaign materials in approaches to medical institutions
- Reinforcing marketing efforts targeting non-orthopedic physicians
- Improving product value (e.g., product enhancement to meet the needs of doctors)



あなたの「歩く」喜びを応援します。

# ひざイキイキ

ひざの痛みに悩まれる方々のための情報WEBサイトです



▼ そのひざの痛みは？

▼ 変形性ひざ関節症について

▼ どんな治療方法があるの？

▼ お医者さんに行く前に

▶ ムービーをスキップ



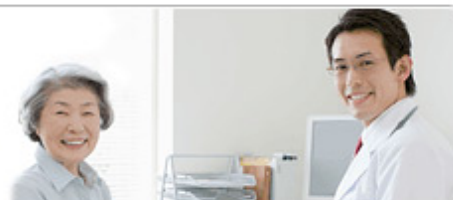
正座を  
しようとしたとき



## お医者さんを探そう

ひざの痛みはお医者さんに相談！

近所のお医者さんを探してみましよう！ [▶ 詳しく見る](#)



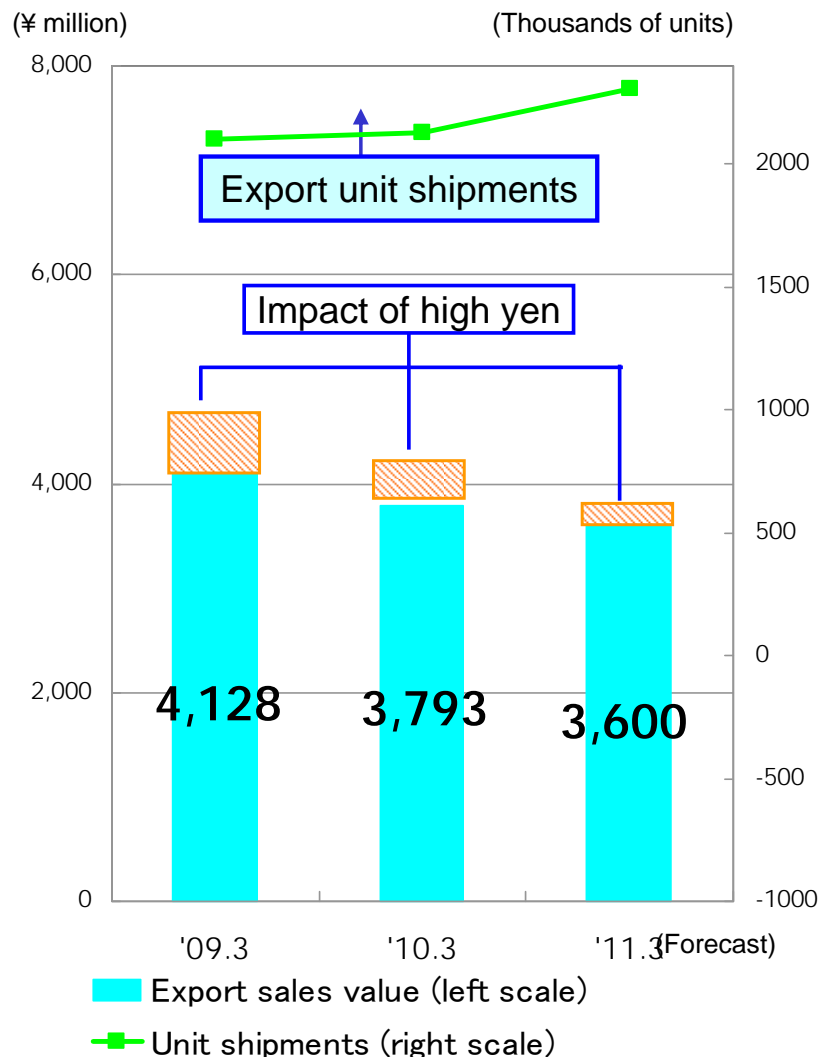
NEW  
ひざの痛みに関する  
▶ アンケート実施中

お答えいただいた  
方にもれなく「ひざ



# ARTZ<sup>®</sup> Export Sales

## ARTZ<sup>®</sup> export sales



(Value of export sales, year-on-year change)

■ Results for FY2009: -8.1%

<US> -8.0%

- **Local sales:**

Tighter reimbursement practice applied by private insurance companies, marginal decline in units sold

- **Seikagaku export sales**

Lower because of high yen (approx. -7%) and lower local selling prices

<**Other markets**> -8.5%

Exports down due to carryover of shipments to China into the following year, but local sales strong (about 30% higher)

■ Forecasts for Year FY2010: -5.1%

<US> -11.5%

- **Local sales:** Continuing harshness of market environment will be reflected in lower unit sales

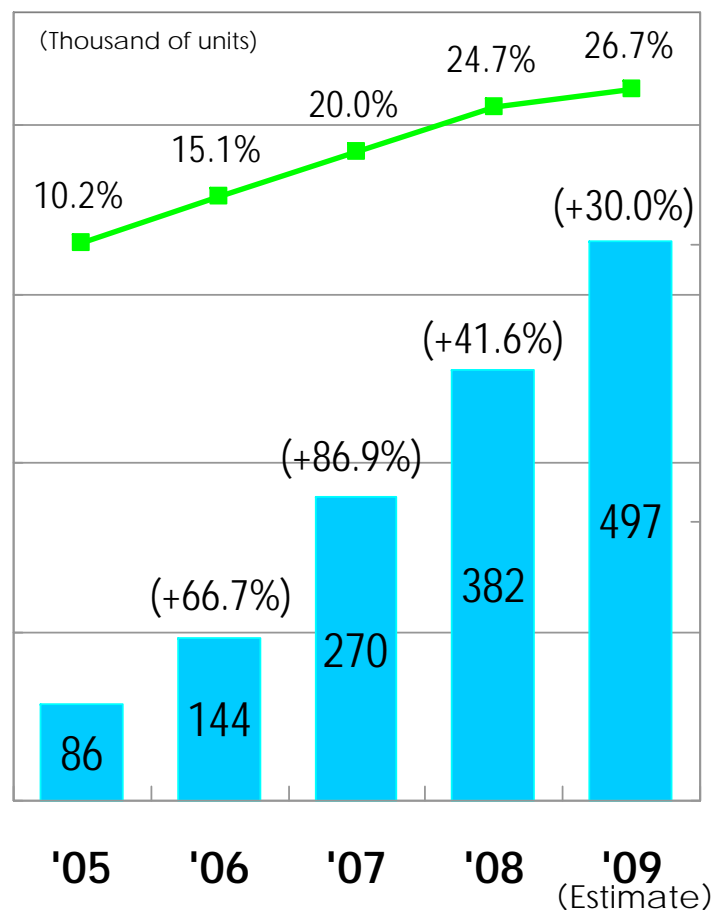
- **Seikagaku export sales:** Decline because of reductions in units shipped and selling prices

<**Other markets**> +16.7%

Local sales in China expected to remain strong

# Chinese Market

## Trends in ARTZ deliveries and share



■ ARTZ deliveries(Units)

■ ARTZ share

(From a research company)

## ■ Trends in Sales of China

- Expansion trend since the switch to a new sales partner, KBN, in 2003. (KBN: A joint venture between a Teva Group company and a local company.)
- Unit deliveries to medical institutions up approx 6 times, compared with the level of 4 years ago

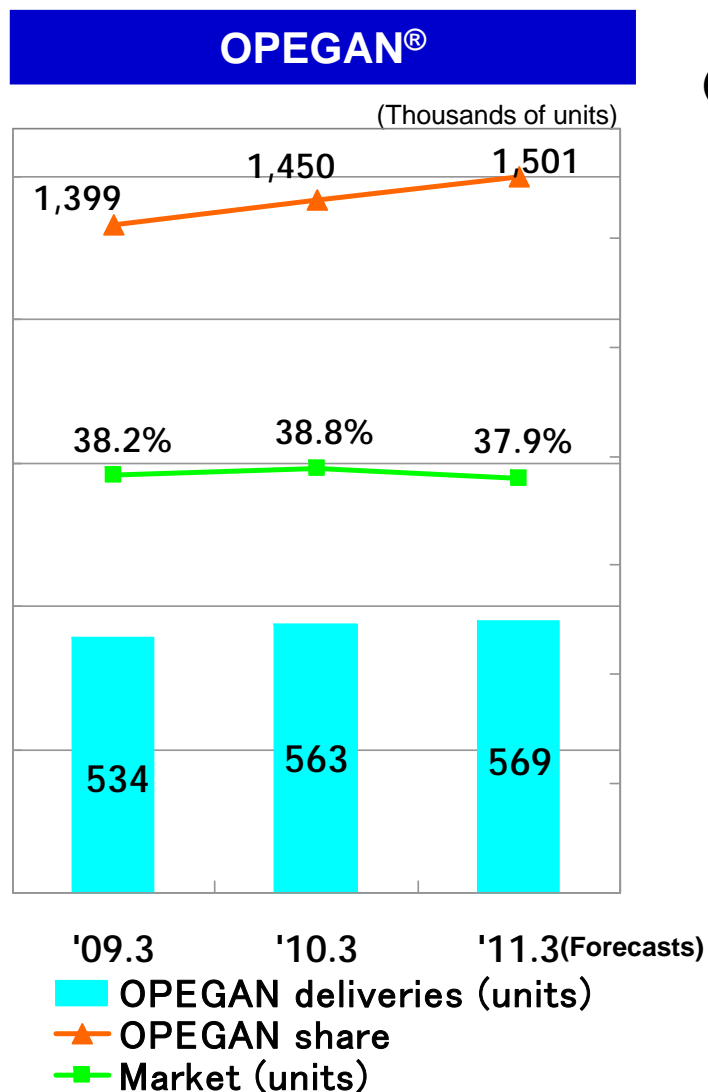
## ■ Environment in the Chinese Pharmaceutical Market

- The market is worth ¥3.2 trillion and is growing by around 30% annually.
- Insurance systems are improving, and the number of people covered has increased in recent years. (Number covered by insurance scheme for urban employees: from 130 mil. in 2005 to 180 mil. in 2008)
- Business risks include system changes and official price revisions.

## ■ Sales Promotion Strategy in China

- We have strengthened our promotional activities, especially in major cities (Beijing, Shanghai, Guangzhou, etc.). In recent years, we have also extended our activities to medium-sized cities.
- We are promoting our brand image as a producer of high-quality, FDA-approved product and its worldwide sales incl. Japan.

# Deliveries of OPEGAN® to Medical Institutions



(Unit deliveries to medical institutions, year-on-year change)

**■ Results for FY2009**

**<Market> +3.6%**

- Increased number of cataract operations in step with growth of aged population

**<OPEGAN®> +5.3%**

- Further expansion of market share

**■ Forecasts for FY2010**

**<Market> +3.5%**

- Market growth rate expected to remain close to previous year's level

**<OPEGAN®> + 1.0%**

- Growth rate to slow because of launch of a new competing product

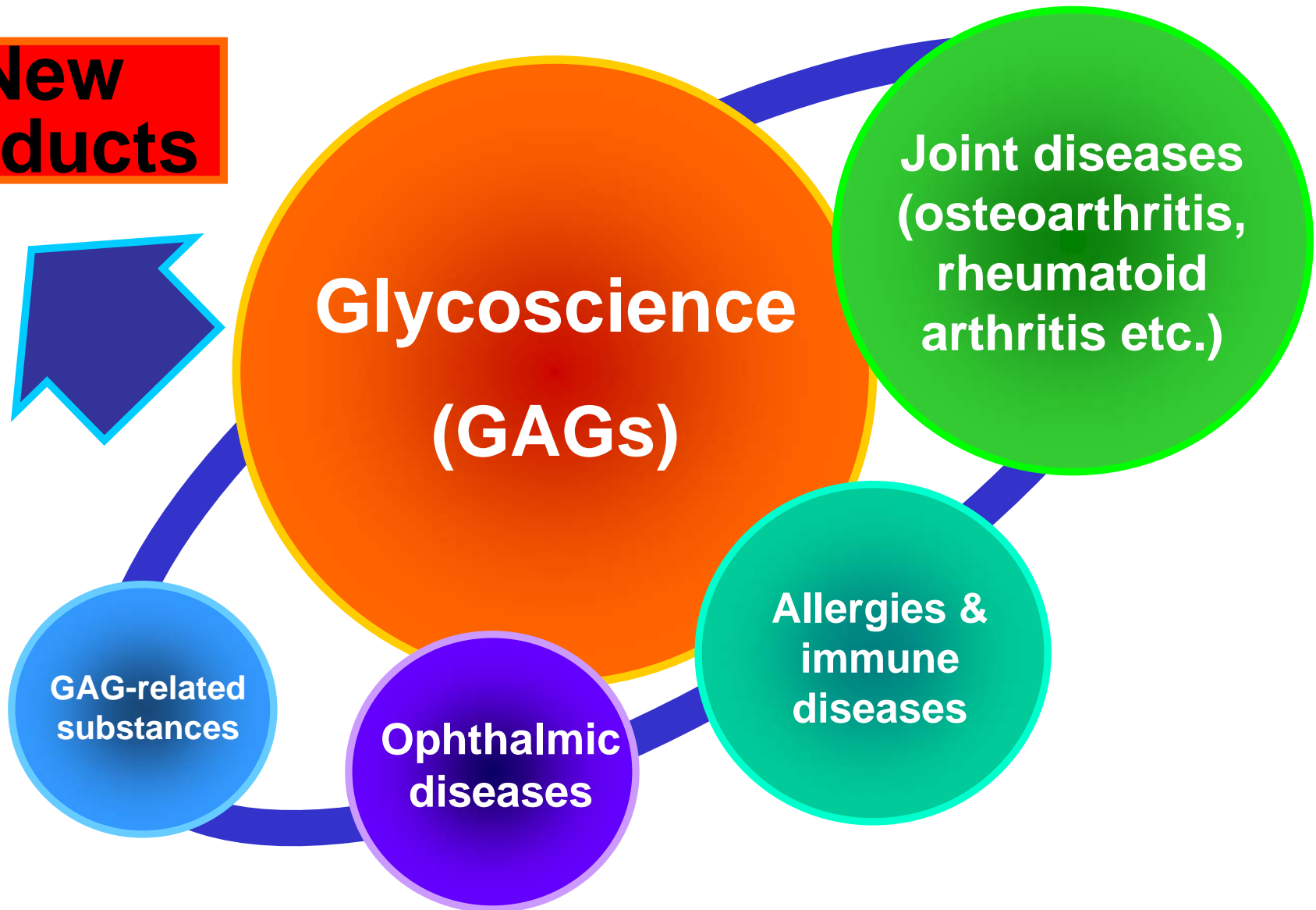
- Sales value lower due to impact of drug price cuts

## **Current Status of the R&D Activities**



# Basic Policy of Research & Development

**New  
Products**



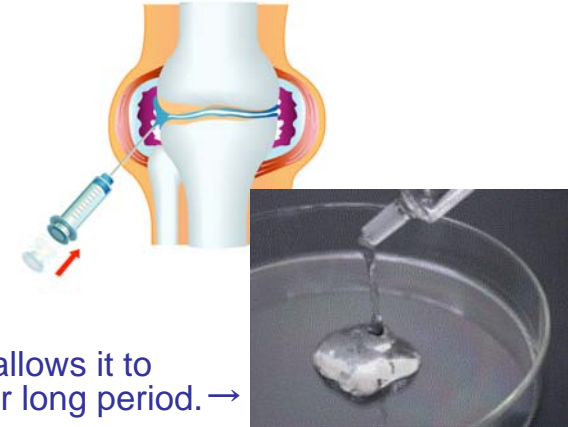
\* GAGs: Glycosaminoglycans (major constituents of glycoconjugates)

# Pipeline List

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

# Gel-200

- ◆ Substancename: Cross-linked hyaluronate hydrogel
- ◆ Indication: Knee osteoarthritis
- ◆ Formulation: Injectable solution (single-injection)
- ◆ Features:
  - Cross-linked hyaluronate hydrogel with extremely high viscoelasticity
  - Provides long-term pain relief with a single intra-articular injection



Its high viscoelasticity allows it to remain in joint cavity for long period. →

## 【Status】

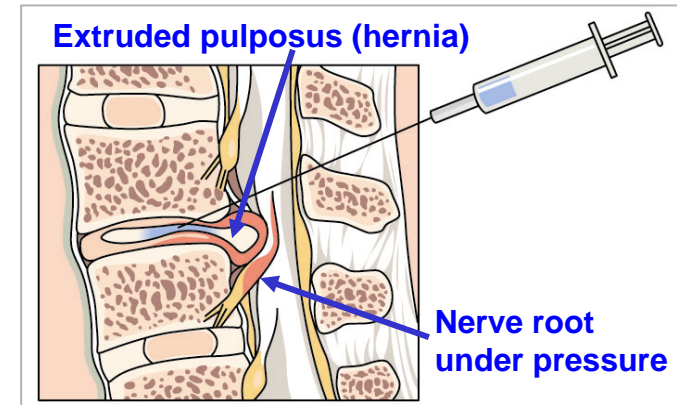
- PMA application submitted to FDA in July 2008
- Results of FDA review received in January 2010  
“Not Approvable”

## 【Follow-up response】

- We are confident in the clinical usefulness of Gel-200 as a medical device and will continue our efforts to secure its approval.
- A major amendment will be submitted to the FDA by the end of June 2010.

# SI-6603

- ◆ Substance name: Chondroitinase ABC
- ◆ Indication: Alleviation of pain caused by lumbar disk herniation
- ◆ Administration: Injection into lumbar disk (under X-ray observation)
- ◆ Features:
  - It alleviates pain by reducing hernia-related nerve pressure through the specific degradation of GAGs (chondroitin sulfate, etc.), the main components of nucleus pulposus.
  - Because SI-6603 does not break down proteins, it has no effect on other tissues (blood vessels, nerves, etc.).
  - A single-injection treatment with SI-6603 is expected to become an alternative to surgery.



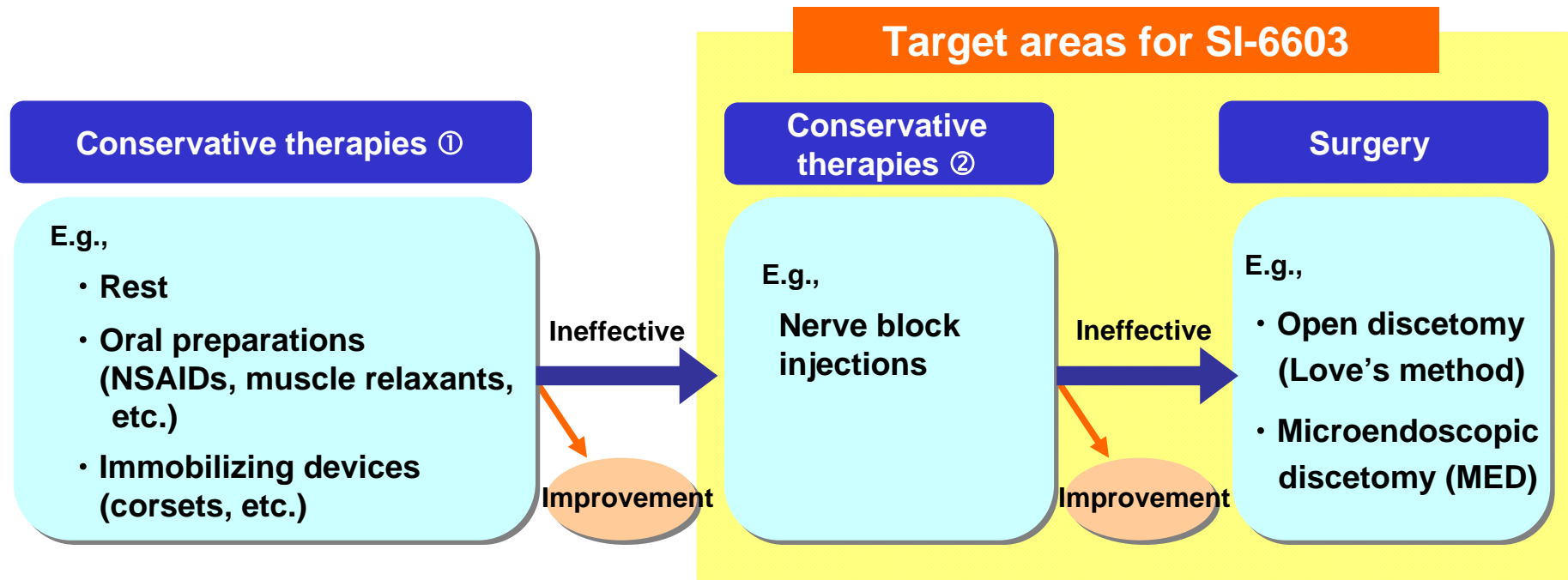
## [Current status]

- **Japan: PII/III** »» Target patient enrollment was completed in August 2009. Progress is now being monitored.



- **U.S: PII** »» In progress

# Target Areas of SI-6603



← Lower back pain, lower limb pain, numbness →

**Number of patients diagnosed with lumbar disk herniation per year  
(Seikagaku estimate)\***

**Japan: 1.1 million**

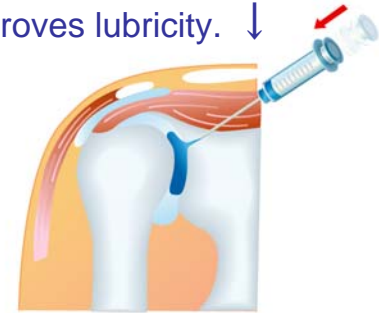
**We estimate that 10–20% of these patients will be treated with SI-6603.**

\* Estimated by Seikagaku using prescription statistics compiled by research companies.

# SI-602

- ◆ Substance: Sodium hyaluronate
- ◆ Indications: Shoulder osteoarthritis (additional indication filed for SPARTZ in the US)
- ◆ Administration method: Injection into the shoulder joint
- ◆ Features:
  - Hyaluronic acid improves lubrication in shoulder joint cavity by coating the cartilage.
  - Developed jointly with our sales partner, Smith & Nephew.
  - If approved, SUPARTZ® will be the first hyaluronic acid product having an indication for shoulder osteoarthritis in the US.
  - Shoulder periarthrititis has already been included in the indications for ARTZ in Japan.

SI-602 coats joint cartilage and improves lubricity. ↓



## 【PIII Clinical Trial Results】

- Statistically significant alleviation of pain compared with the placebo group
- No major safety issues

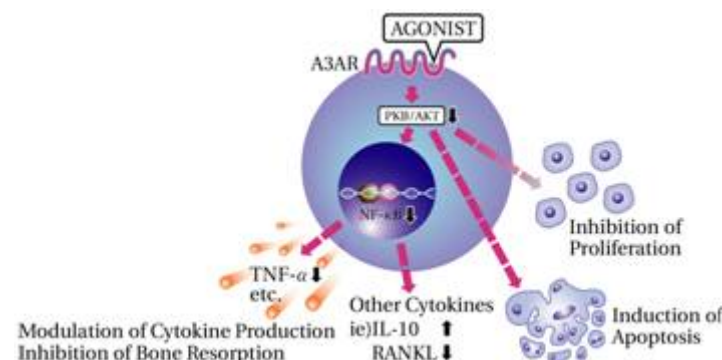
## 【Current Stage】

- PMA submitted to the FDA on September 25, 2009 is now in review

# SI-615

- ◆ Substance: Adenosine A3 receptor agonist
- ◆ Indications: Rheumatoid arthritis
- ◆ Administration method: Oral
- ◆ Features:
  - Licensed from CanFite BioPharma
  - This substance is thought to suppress intracellular signal transduction involving pathogenesis of inflammation and the production of proinflammatory cytokine.

This substance binds selectively to adenosine A3 receptors, highly exposed in inflammatory regions.



## 【Current stage】

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

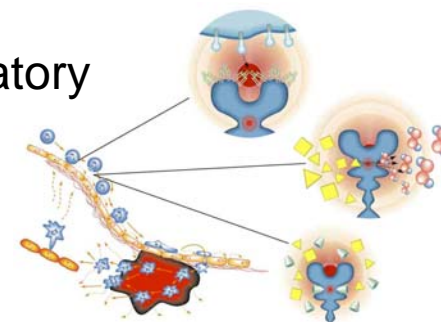
## 【Progress】

- CanFite currently planning PIIb monotherapy trial

# SI-636

- ◆ Substance: Anti-VAP-1 monoclonal antibody
- ◆ Indications: Inflammatory diseases  
(Target diseases: Rheumatoid arthritis, psoriasis, inflammatory bowel disease)
- ◆ Administration method: Intravenous injection
- ◆ Features :
  - Licensed from BioTie Therapies
  - Expected to prevent inflammation by inhibiting VAP-1, an adhesion molecule involved in the accumulation and invasion of white blood cells at inflammation sites

Inhibit Vap-1, which is thought to cause inflammation by contributing to the accumulation of leukocytes and their invasion into the site of inflammation. ↓



## 【Current Stage】

- Pre-clinical in Japan
- PI in Europe by BioTie

## 【Progress】

- BioTie completed a Phase I repeat-dose study for rheumatoid arthritis
- No serious side-effects, and tolerability confirmed

**Improvement Measures for Shareholder's value**



# 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%.

### Dividend forecast for FY2009

Annual ¥25.00 (interim ¥12.50)

Dividend payout ratio 39.7%

## 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



# 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** GPS (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

# Appendix

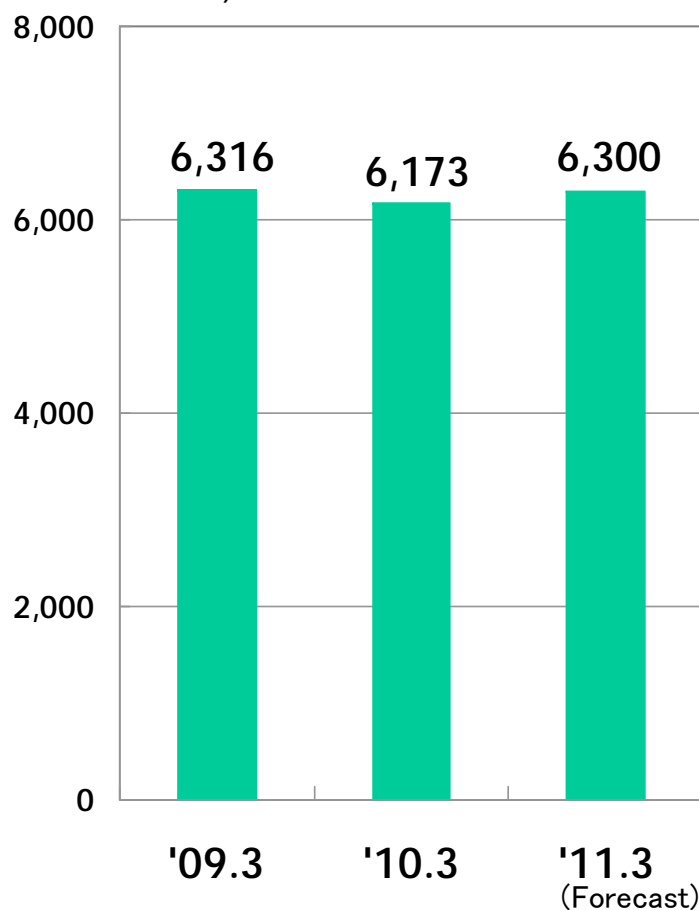


# Sales of Fine Chemicals

## Fine Chemicals

(Sales value , year-on-year change)

(Million of Yen)



**FY2009 Results -2.3%**

**[Bulk Products] +6.8%**

Sales of hyaluronic acid higher because of increased sales of products in which it is used

**[Research Reagents & Diagnostics] -5.1%**

Strong domestic sales, especially of endotoxin-detecting reagents for use in quality control, but overseas sales lower because of high yen

**FY2010 Forecasts +2.0%**

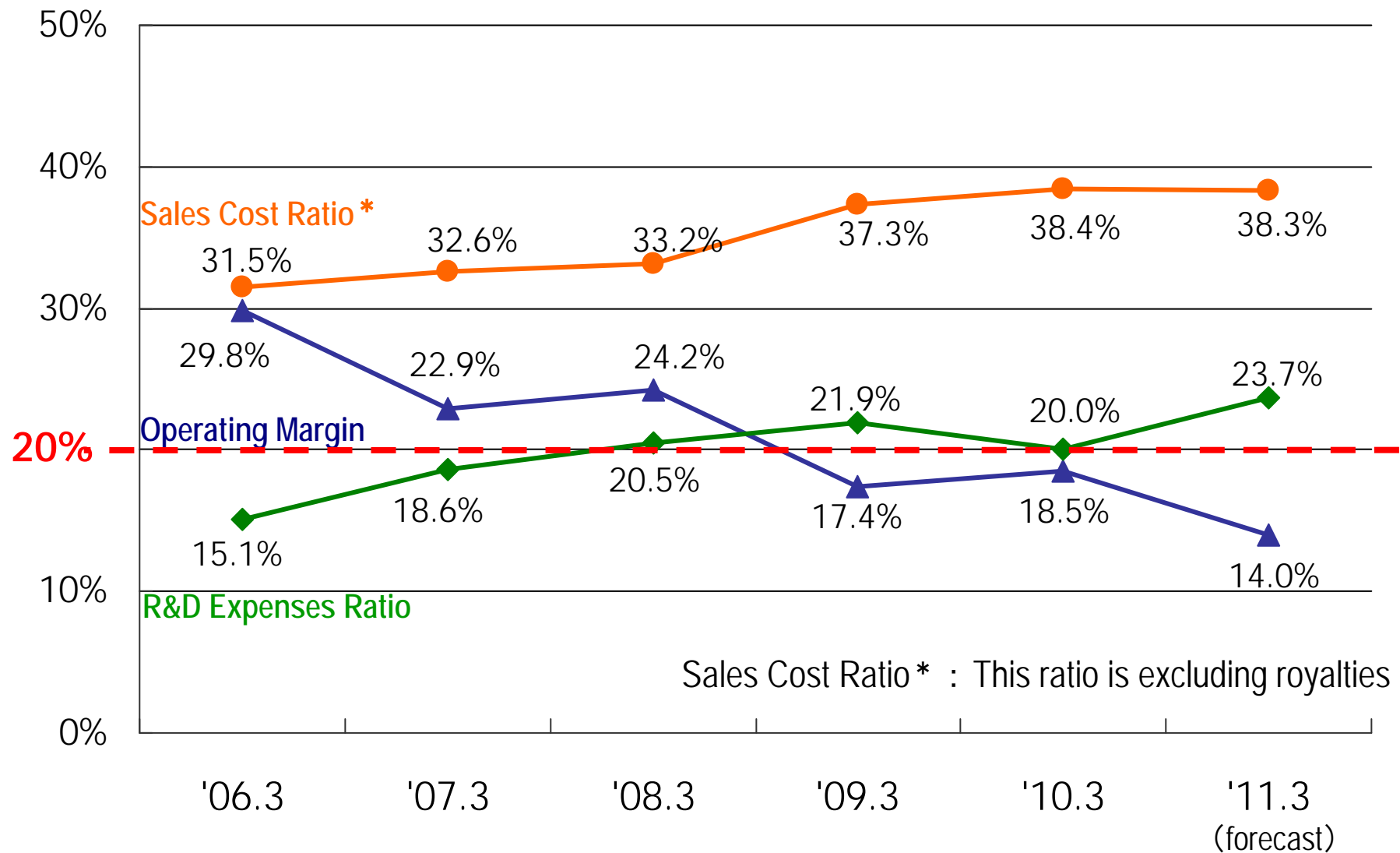
**[Bulk Products] +6.7%**

Continued strong sales of hyaluronic acid

**[Research Reagents & Diagnostics] +0.4%**

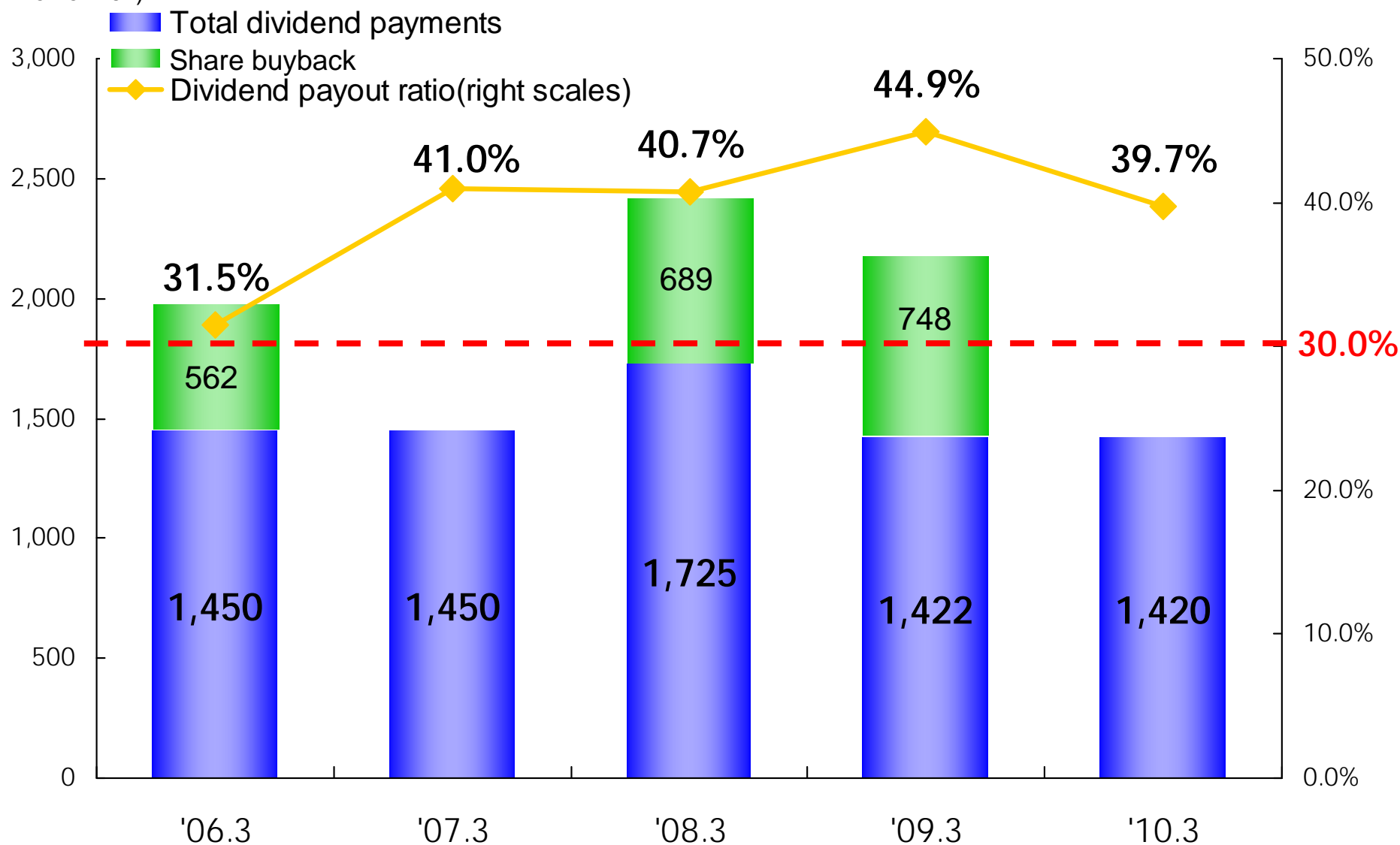
Reduction in domestic sales of reagents offset by increased overseas sales of endotoxin-detecting reagents, total expected to be similar to previous year's results

# Trend in Financial Index



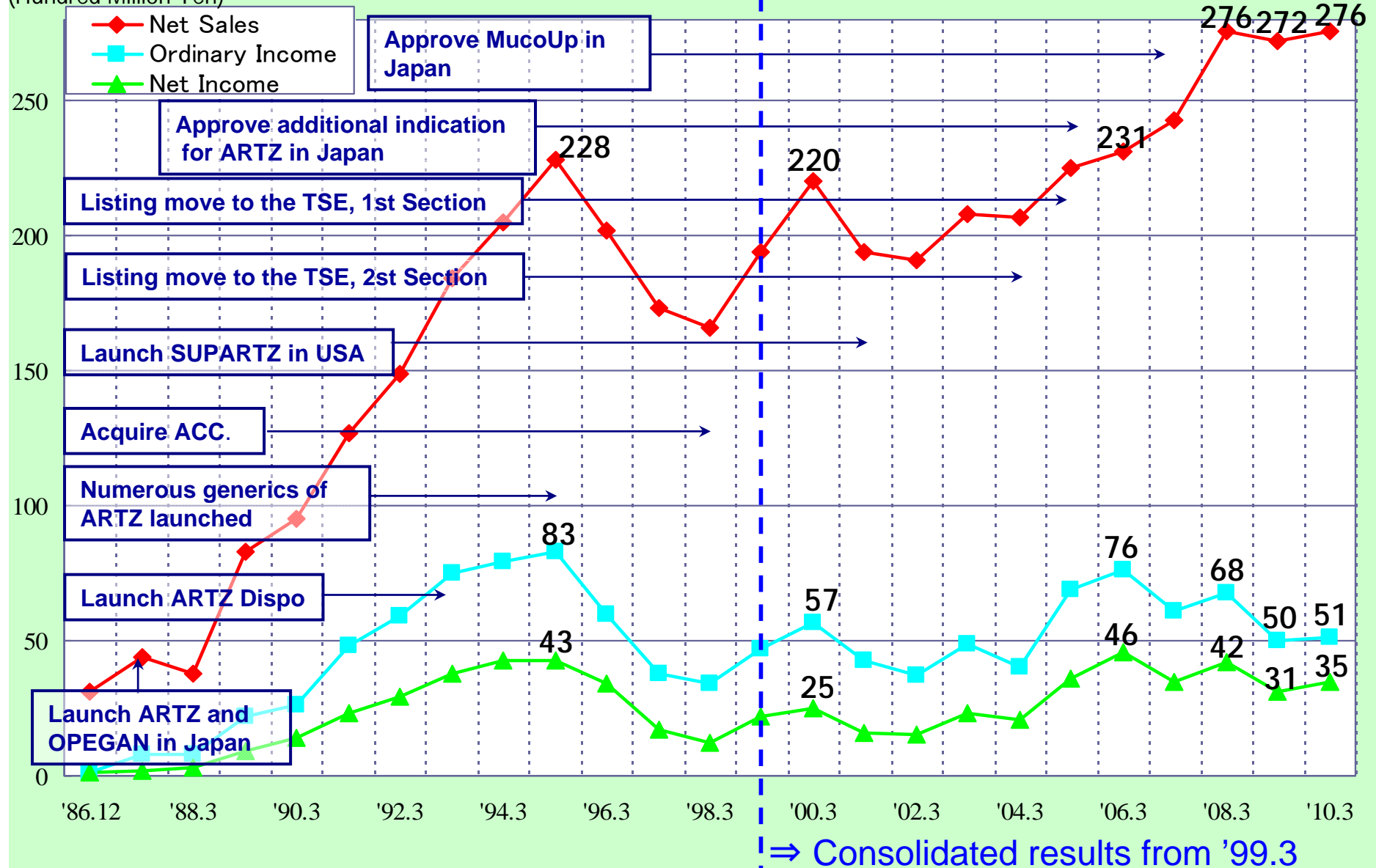
# Trend in Dividend and Share Buyback

(Million of Yen)



# Business Progress & Highlights

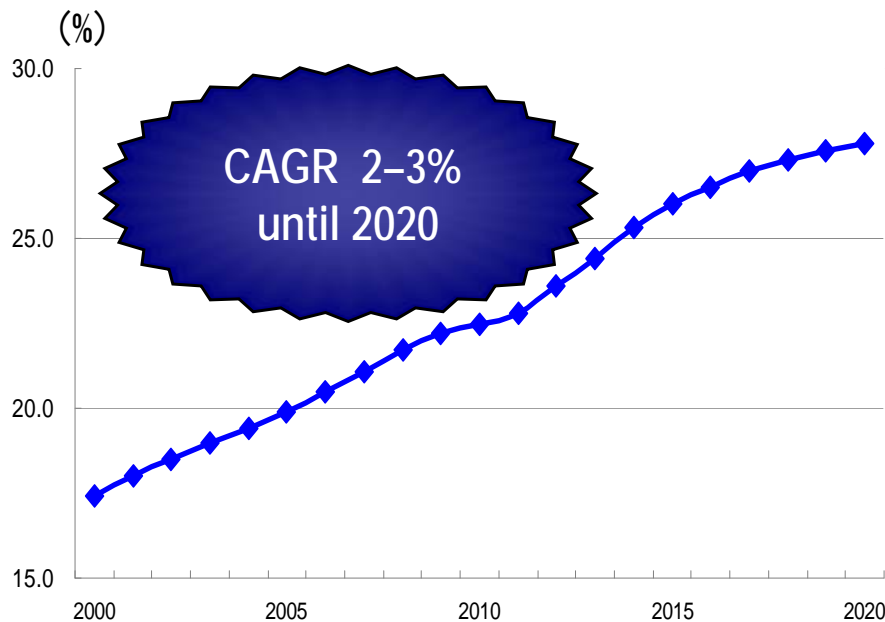
(Hundred Million Yen)



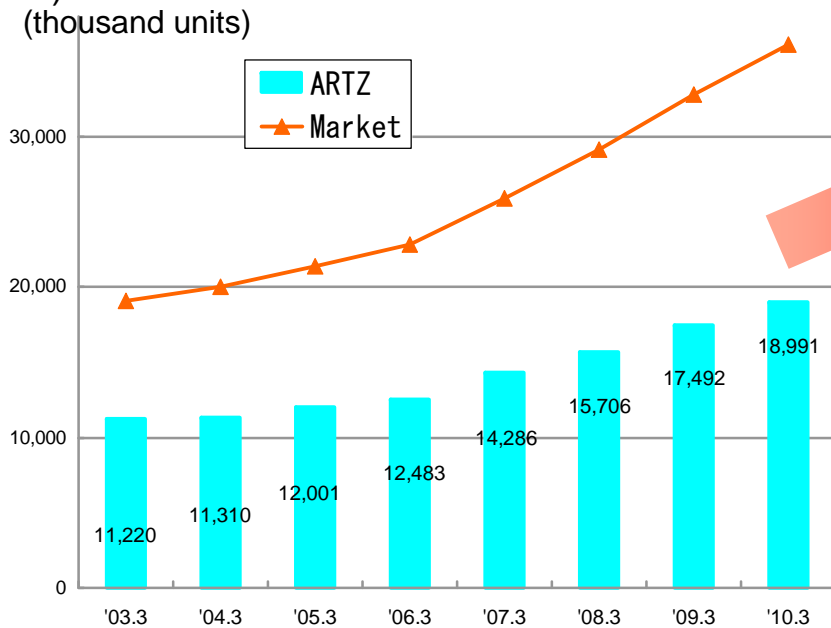
# Expanding Market of ARTZ in Japan

- 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 Tokyo University)

## ■ Growing Elderly Population (65 or over) (Source: Ministry of Internal Affairs and Communications)

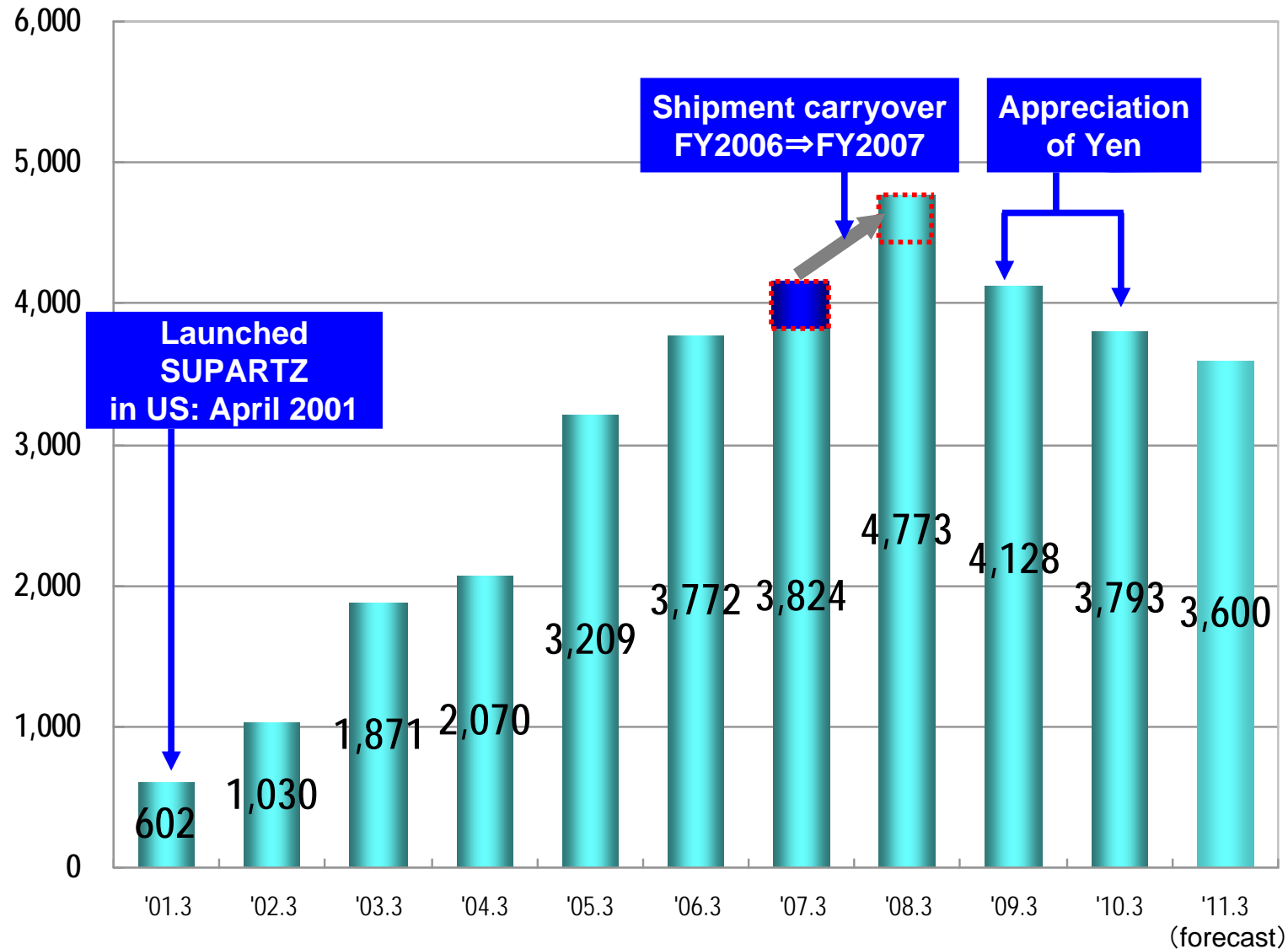


## ■ Deliveries of ARTZ to Medical Institutions (Japan)



# Trend in Hyaluronic Acid Products in Overseas Market

(Million of Yen)



# Development of Projects - 1

## Gel-200 (cross-linked hyaluronate hydrogel)

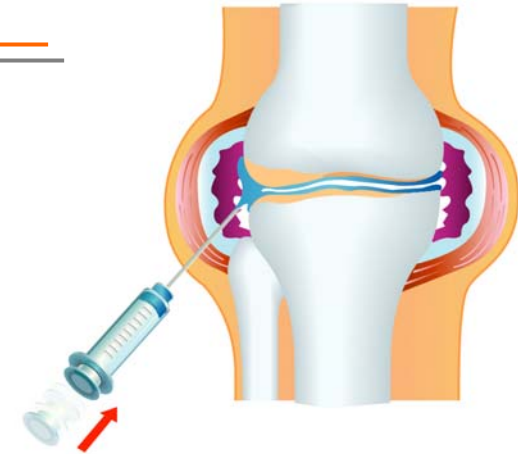
- **Indication:** Knee osteoarthritis
- **Status:** Filed for approval(US)
- **Formulation:** Injectable solution (medical device)
- **Origin:** In-house
- **Profile:**

This is an injectable solution for the treatment of osteoarthritic knee joints. Its main ingredient is cross-linked hyaluronate hydrogel manufactured using an exclusive cross-linking technology. A single injection is expected to provide long-term pain relief, because the extremely high viscoelasticity of the solution allows it to remain in the knee-joint cavity for long periods of time.

- **Description:**

# Application submitted with FDA on July, 2008. Receipt of Result “Not Approvable” on January,2010.

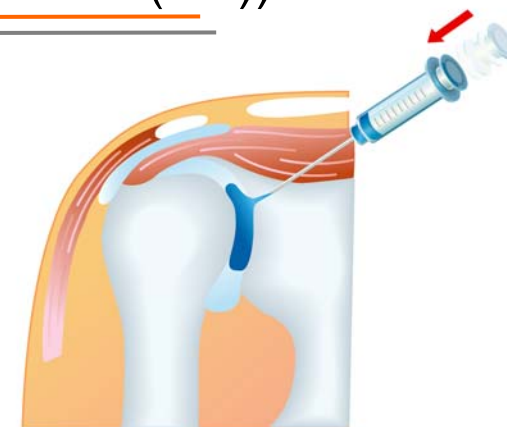
# A major amendment will be submitted to the FDA by the end of June 2010.



# Development of Projects -2

## SI-602 (Hyaluronic acid/additional indication for SUPARTZ (US))

- **Indication:** Shoulder osteoarthritis
- **Status:** Filed for approval(US)
- **Formulation:** Injectable solution (medical device)
- **Origin:** Collaborative development (Smith & Nephew, Inc)



- **Profile:**

Shoulder osteoarthritis is a disease that causes degeneration, ablation, swelling, pain, and motor dysfunction of the joint cartilage, due to excessive burden over long periods, mainly on the shoulders. The superior viscoelasticity of hyaluronic acid is expected to protect joint cartilage, and improve lubricity. In Japan, ARTZ is approved for the treatment of shoulder periarthritis.

- **Description:**

# Application submitted in September 25, 2009

# Development of Projects - 3

## SI-6603 (chondroitinase ABC)

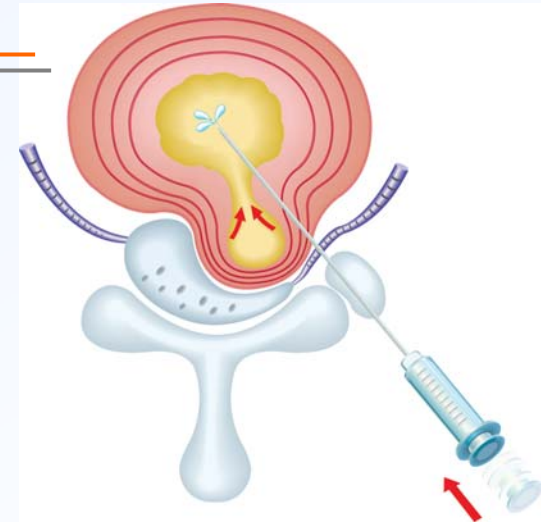
- **Indication:** Lumbar disk herniation
- **Status:** Phase II/III (Japan)  
Phase II (US)
- **Formulation:** Injectable solution
- **Origin:** In-house
- **Profile:**

Chondroitinase ABC is a GAG-degrading enzyme produced from bacteria. It degrades chondroitin sulfate, a principal component of nucleus pulposus. A single injection of SI-6603 into a herniated lumbar disk is expected to provide efficacy similar to that of surgery.

- **Description:**

- # Target patient enrollment in Japan was completed in August 2009.

- # Progress monitoring to be completed in August 2010,  
Application approval planned in Mid-2011.



# Development of Projects - 4

## SI-615 (Adenosine A3 receptor agonist)

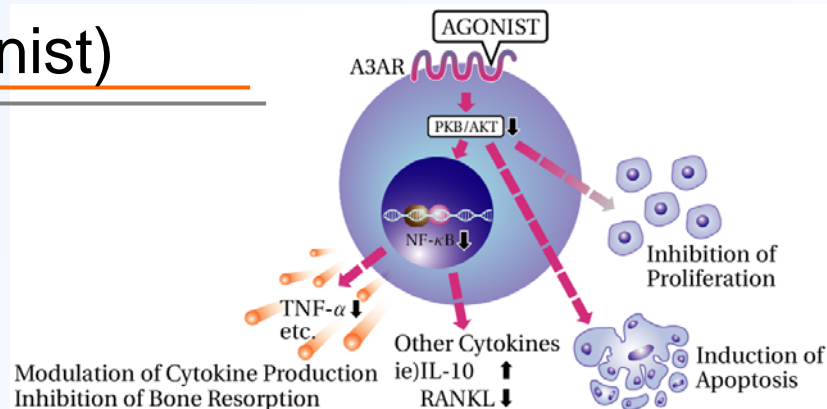
- **Indication:** Rheumatoid arthritis
- **Status:** Phase I (Japan)
- **Formulation:** Oral agent
- **Origin:** In-license from Can-Fite BioPharma Ltd.

### ■ Profile

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. This receptor agonist is expected to become a highly safe anti-inflammatory agent that offers a new mechanism of action.

### ■ Description:

- # Phase I single administration clinical trial in Japan ended
- # Results of Phase IIb trial (follow-up trial) carried out by CanFite in Europe and Israel announced on April 30, 2009. Superiority to placebo not found at primary endpoint.
- # Canfite is planning IIb monotherapy trial.



# Development of Projects -5

## SI-636 (Anti-Vap-1 antibodies)

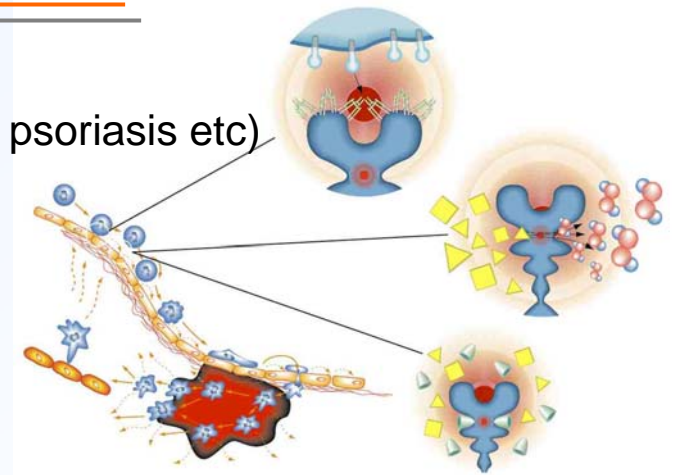
- **Indication:** Inflammatory diseases  
(Target disease:rheumatoid arthritis, psoriasis etc)
- **Status:** Pre-clinical (Japan)
- **Formulation:** Injectable solution
- **Origin:** In-license from BioTie Therapies Corp.

- **Profile:**

Anti-Vap-1 antibodies inhibit Vap-1, which is thought to cause inflammation by contributing to the accumulation of leukocytes and their invasion into the site of inflammation. Conventional anti-inflammatory agents suppress the generation or inhibit the action of inflammatory substances, while SI-3106 uniquely acts on the adhesion molecules controlling leukocyte movement.

- **Description:**

# Phase I repeated dose study for rheumatoid arthritis conducted by BioTie completed. There were no severe side effects, and tolerability was confirmed.(BioTie announced on January 19, 2010 )



## 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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