

Exploring the Innovative Promise of Glycoscience

Financial Results for the 1H of FY2011

(April 1, 2011-September 30, 2011)



SEIKAGAKU CORPORATION



<http://www.ehiza.jp>

(TSE:4548)



Financial results for 1H

(Millions of Yen)

	FY2011 1H Results	vs.FY2010 1H Results	vs. 5/11Initial Forecast for 1H	vs. 9/28 Revised Forecast for 1H
Net Sales	13,795	-87 (-0.6%)	-404 (-2.8%)	-4 (-0.0%)
Operating Income	3,213	+1,413 (+78.6%)	+913 (+39.7%)	-86 (-2.6%)
Ordinary Income	3,183	+1,466 (+85.4%)	+783 (+32.7%)	-16 (-0.5%)
Net Income	2,109	+931 (+79.1%)	+609 (+40.6%)	+9 (+0.5%)
R&D Expenses	2,422	-1,062 (-30.5%)	-877 (-26.6%)	+22 (+1.0%)
R&D Expenses Ratio (to Net Sales)	17.6%	-7.5pt	-5.6pt	+0.2pt
Net Income Per Share	¥37.13	+¥16.39	+¥10.73	+¥0.16

Average Exchange Rate (¥/US\$)

79.81

88.95

83.00

79.83



Net Sales for 1st Half of FY2011 (compared with FY2010/1H)

Net sales: ¥13,795 (-¥87, -0.6%)

(Millions of yen)

【Pharmaceuticals: ¥10,981 (-¥73)】

-Japan (-¥93) *Across-the-board negative impact of the earthquake

ARTZ[®]: Lower market growth rate, but higher market share

Seikagaku sales at roughly the prior-1H level following high sales in FY2010/1H

OPEGAN[®]: Decline as a result of fewer operations due to concerns about power outages and intensified competition

MucoUp[®]: Increase despite the impact of a supply shortage of surgical instruments

- Overseas (+¥20) *Impact of yen appreciation (-¥150)

United States: Local sales at the prior-1H level. Decrease in export sales due to the impact of yen appreciation, despite higher export volumes

Other Markets: Continued strong local sales in China. Increase in sales to the EU from shipments carryover from FY2010

【Fine chemicals: ¥2,814 (-¥13)】

Research Reagents and Diagnostics (-¥55): Impact of yen appreciation and lower domestic sales (ACC sales higher on local currency basis)

Bulk products (+¥41): Increased sales of hyaluronic acid

◆Point: Sales at roughly the prior-1H level as increases in sales of pharmaceuticals overseas and bulk hyaluronic acid compensated for a decline in domestic pharmaceuticals sales due to the earthquake and the impact of yen appreciation



Income for 1st Half of FY2011 (compared with FY2010/1H)

(Millions of yen)

Operating income: ¥3,213 (+¥1,413, +78.6%)

【Cost of sales (-¥475)】

Decrease in depreciation of the No. 4 Production Building and product mix factors

*Cost of sales ratio: 35.8% (-3.2 pt)

【SG&A expenses (-¥1,025)】

R&D expenses: ¥2,422 (-¥1,062) SI-6603-related expenses: Decrease in clinical trial expenses in Japan.

Slippage of U.S. clinical trial expenses to the second half

Net income: ¥2,109 (+¥931, +79.1%)

【Foreign exchange losses (-¥139)】

Decrease in foreign exchange losses related to valuation of foreign currency assets

【Extraordinary losses (+¥19)】

Losses from the earthquake (+¥71)

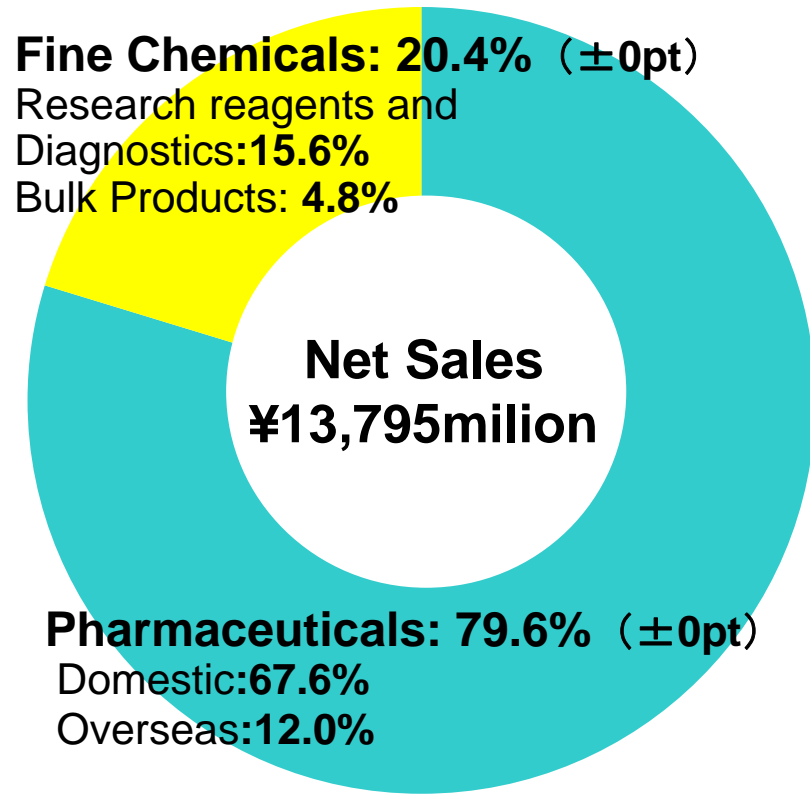
Absence of asset retirement obligation expenses posted in the previous year (-¥51)

◆Point: Income increase attributable to lower cost of sales and higher gross profit as a result of factors including lower depreciation and R&D expenses, principally SI-6603-related expenses

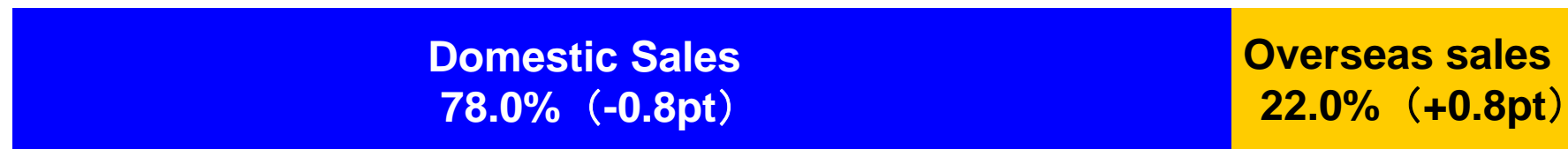


Net Sales by Business Segment

(Millions of Yen)



Segment	Net Sales	vs. Previous Period	Change
[Pharmaceuticals]	10,981	-73	-0.7%
Domestic Pharmaceuticals	9,330	-93	-1.0%
Overseas Pharmaceuticals	1,650	+20	+1.3%
[Fine Chemicals]	2,814	-13	-0.5%
Research Reagents and Diagnostics	2,156	-55	-2.5%
Bulk Products	658	+41	+6.8%
Total	13,795	-87	-0.6%
(Overseas Sales)	3,030	+87	+3.0%





FY2011 1st Half Results (Compared with Initial Forecast)

(Millions of yen)

Net sales: ¥13,795 (-¥404, -2.8%)

- Pharmaceuticals (-¥318): Trend holding off medical consultations and fewer operations following the earthquake and the impact of yen appreciation
- Fine chemicals (-¥85): Despite a one-time sales increase on termination of sales of research reagents, carryover of some shipments of bulk hyaluronic acid to the second half

Operating income: ¥3,213 (+¥913, +39.7%)

- SG&A expenses (-¥1,151)
Decrease in R&D expenses (-¥877) / Forecast: ¥3,300 ⇒ ¥2,422
⇒ Slippage of SI-6603 U.S. clinical trial expenses to the second half, decrease in selling expenses

Net income: ¥2,109 (+¥609, +40.6%)

- Increase in non-operating expenses: Increase in foreign exchange loss

◆ **Point:** Lower net sales than forecast due to a decrease in domestic pharmaceuticals sales and carryover of shipments of bulk hyaluronic acid. Higher income than forecast due to the slippage of U.S. SI-6603 clinical trial expenses to the second half



Overview of Forecast for FY2011

(Millions of Yen)

	FY2011 Revised Forecast	Initial Forecast	vs. Initial forecast	FY2010 Results	vs. Previous Year
Net Sales	27,000	28,000	-1,000 (-3.6%)	27,117	-117 (-0.4%)
Operating Income	4,700	4,800	-100 (-2.1%)	3,533	+1,166 (+33.0%)
Ordinary Income	4,800	5,100	-300 (-5.9%)	4,159	+640 (+15.4%)
Net Income	3,200	3,300	-100 (-3.0%)	2,451	+748 (+30.5%)
R&D Expenses	5,700	5,900	-200 (-3.4%)	6,723	-1,023 (-15.2%)
R&D Expenses Ratio (to Net Sales)	21.1%	21.1%	—	24.8%	-3.7pt
Net Income Per Share	¥56.33	¥58.09	-¥1.76	¥43.16	+¥13.17

Average Exchange
Rate (¥/US\$)

¥77.00

¥83.00

¥85.72

(2nd half forecast)



Revised FY2011 Forecasts (Compared with Initial Forecast)

(Millions of yen)

Net sales: ¥27,000 (-¥1,000, -3.6%)

- Decrease in domestic pharmaceuticals sales from impact of the earthquake, etc (-¥1,000)
- Volume increase in overseas pharmaceuticals (the U.S. and China) to compensate for the impact of yen appreciation

*Impact of yen appreciation on overall sales (Approx. -¥280)

Operating income: ¥4,700 (-¥100, -2.1%)

- SG&A expenses (approx. -¥500)
 - Decrease in R&D expenses (-¥200)/Forecast: ¥5,900 ⇒ ¥5,700
⇒ Decrease in sundry expenses
 - Decrease in selling expenses (-¥200)
⇒ Decrease in domestic pharmaceuticals sales

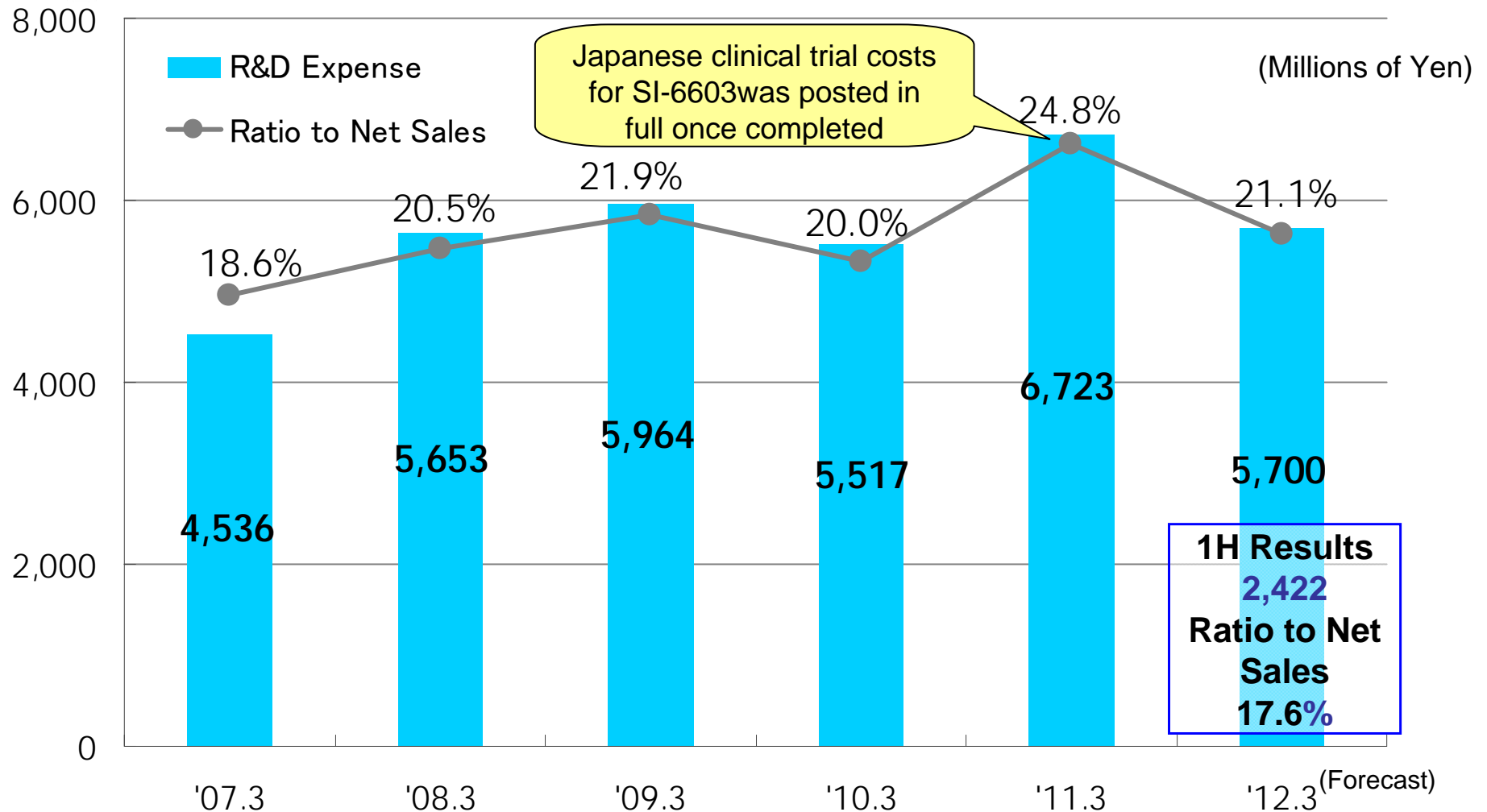
Net income: ¥3,200 (-¥100, -3.0%)

- Increase in non-operating expenses: Increase in foreign exchange losses related to valuation of foreign currency assets

◆**Point:** Initial net sales forecast lowered because of a decrease in domestic pharmaceuticals sales due to the impact of the earthquake. Income to decrease slightly as lower S&G expenses fail to compensate for the sales decrease in gross profit.



Trend in R&D Expense and Ratio to Net Sales



◆ **Point:** Although there were no major expenditures in the first half, the recording of SI-6603 U.S. PII clinical trial expenses in the second half is expected.

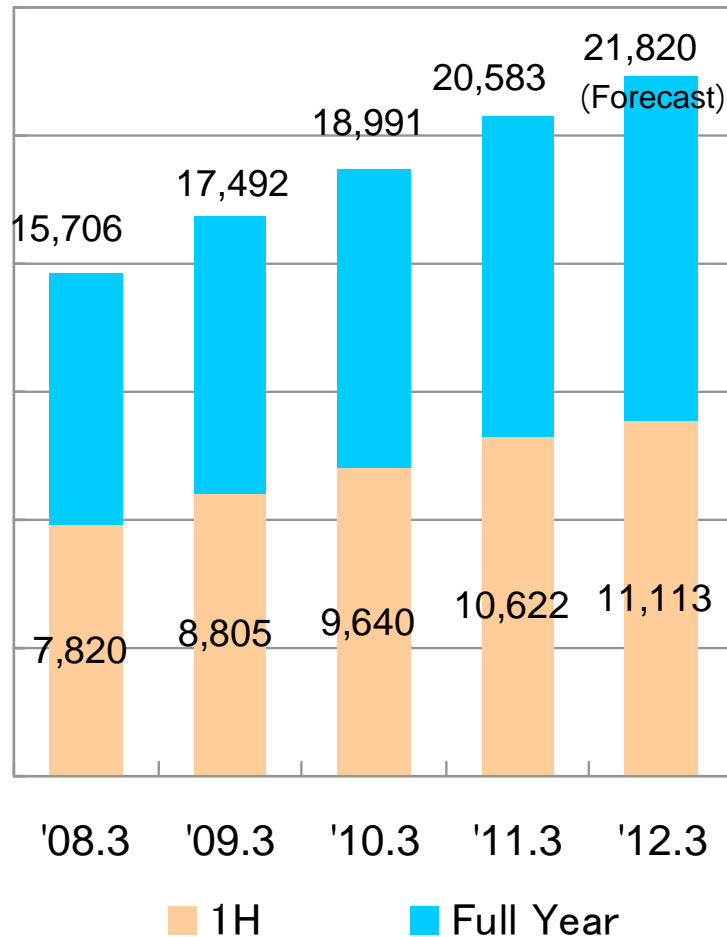




Domestic Sales of ARTZ[®] (unit deliveries to medical institutions)

ARTZ[®] Deliveries to Medical Institutions

(Thousand units)



■ FY2011 1H Results (compared with F2010/1H)

<<Market>>: +3.2%

- Lower growth rate due to trend holding off medical consultations following the earthquake

<<ARTZ[®]>>: +4.6%

- Enhanced brand potential as the original product
- Introduction of a plastic syringe products

⇒ARTZ[®] is the market driver

Market share increase: 54.4% [+0.7 pt]

■ FY2011 Full-year Forecasts (year-on-year)

<<Market>>: +3.9%

<<ARTZ[®]>>: +6.0%

- Anticipated recovery from the earthquake starting in the second half

- Increase in the consultation rate thanks to a continuing disease awareness campaign, and implementation of measures to increase the 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

Market expansion by disease awareness campaign



Advertising in the nationwide morning edition of the *Yomiuri Newspaper* (Sept. 2011)



Rebroadcast of a disease awareness program on TV Tokyo affiliated stations (Sept. 2011)



Addition of "Knee Pain and Adult Diseases" as new content on the disease awareness website

Expanding ARTZ in prescriptions

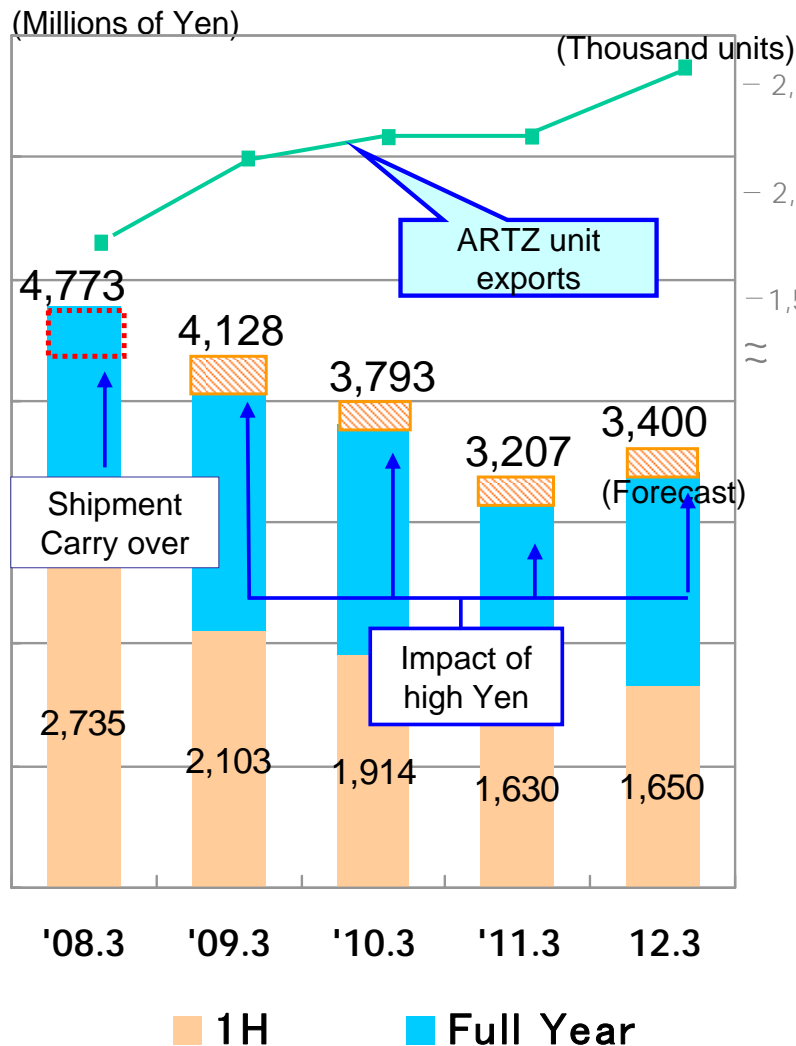
- Responding to needs of medical fields by offering both plastic and glass syringes
- Approaches to medical institutions using brochures and other disease awareness materials
- Increased sales promotion efforts targeting medical specialties other than orthopedic surgeons





Overseas Pharmaceuticals Sales (value basis)

Overseas Pharmaceuticals Sales



■ FY2011 1H Results: +1.3% (compared with FY2010/1H)

<<United States>>

-Local sales: -0.3%

The impact of non-endorsement by some insurance companies nearly took a round. Unit prices turned to recovery from drop due to price maintenance efforts

-Seikagaku export sales: -6.8%

Despite an export volume increase due to the distributor's inventory policy in light of the sales trend, a decline due to yen appreciation (approx. -10%)

<<Other markets>>

- Seikagaku export sales: +19.5%

Increase on higher sales in China (+25%) and carryover of shipment to the EU postponed from FY2010

■ FY2011 Full-year Forecasts +6.5% (year-on-year)

<<United States>>

- Local sales: Planned sales at the FY2010 level to result from utilization of a disease awareness website and cultivation of needs for a multiple-injection product

- Seikagaku export sales: -2.4%

Decrease due to yen appreciation (approx. -9%) despite a volume increase

<<Other markets>> +29.4%

Continued strong sales to China



The Market Situation in China

Market Information

Urban population: 665 mil. → **The no. of insured surpasses the 300 mil. milestone**

- ◆ No. of insured as a result facilitating insurance systems (as of 2008)
Basic Medical Insurance for Urban Employees 180 million insured (40% increase in 3 years)
Basic Medical Insurance for Urban Residents 120 million insured

Sales of ARTZ[®]

(FY2011/Q2)

Local sales growth rate: **25% (8 consecutive years of double-digit growth)**
Market share (estimated): **Higher than 20% (ranked 2nd)**
Proportion of ARTZ[®] export volume: **36% (6.1-fold increase in 5 years)**

Sales Strategy

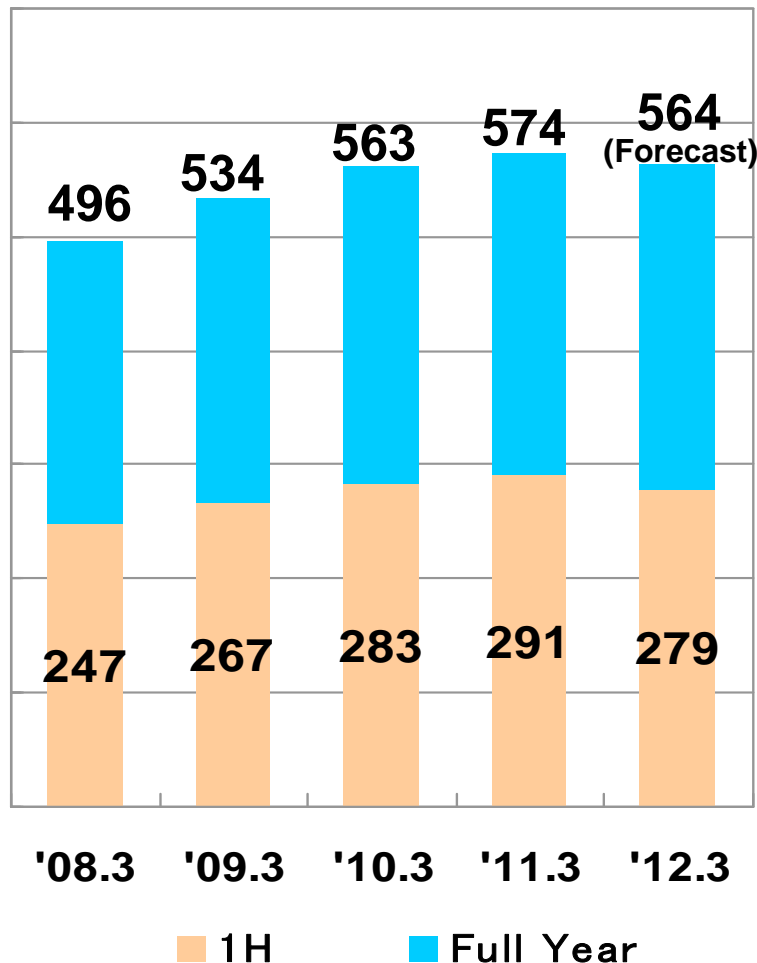
- ◆ Leverage appeal as World's original product, high quality, publicity as a product that has received FDA approval
- ◆ Development of business at large hospitals, mainly in urban areas (nearly complete coverage of key hospitals)
- ◆ Focus on measures to increase prescriptions



Sales of OPEGAN[®] (unit deliveries to medical institutions)

OPEGAN[®] deliveries to Medical Institutions

(Thousand units)



■ FY2011 1H Results (compared with FY2010/1H)

<<Market>>: -0.0%

- Fewer operations due to the earthquake, rolling power blackouts, and power saving

<<OPEGAN[®]>>: -3.9%

- Sales decline due to intensified competition
- Gradual recovery trend from August onward

■ 2011 Full-year Forecasts (year-on-year)

<<Market>>: +1.0%

- Outlook for lessening of impact from the earthquake
⇒ Forecasted 2H sales of roughly the FY2010 2H level (+2.0%)

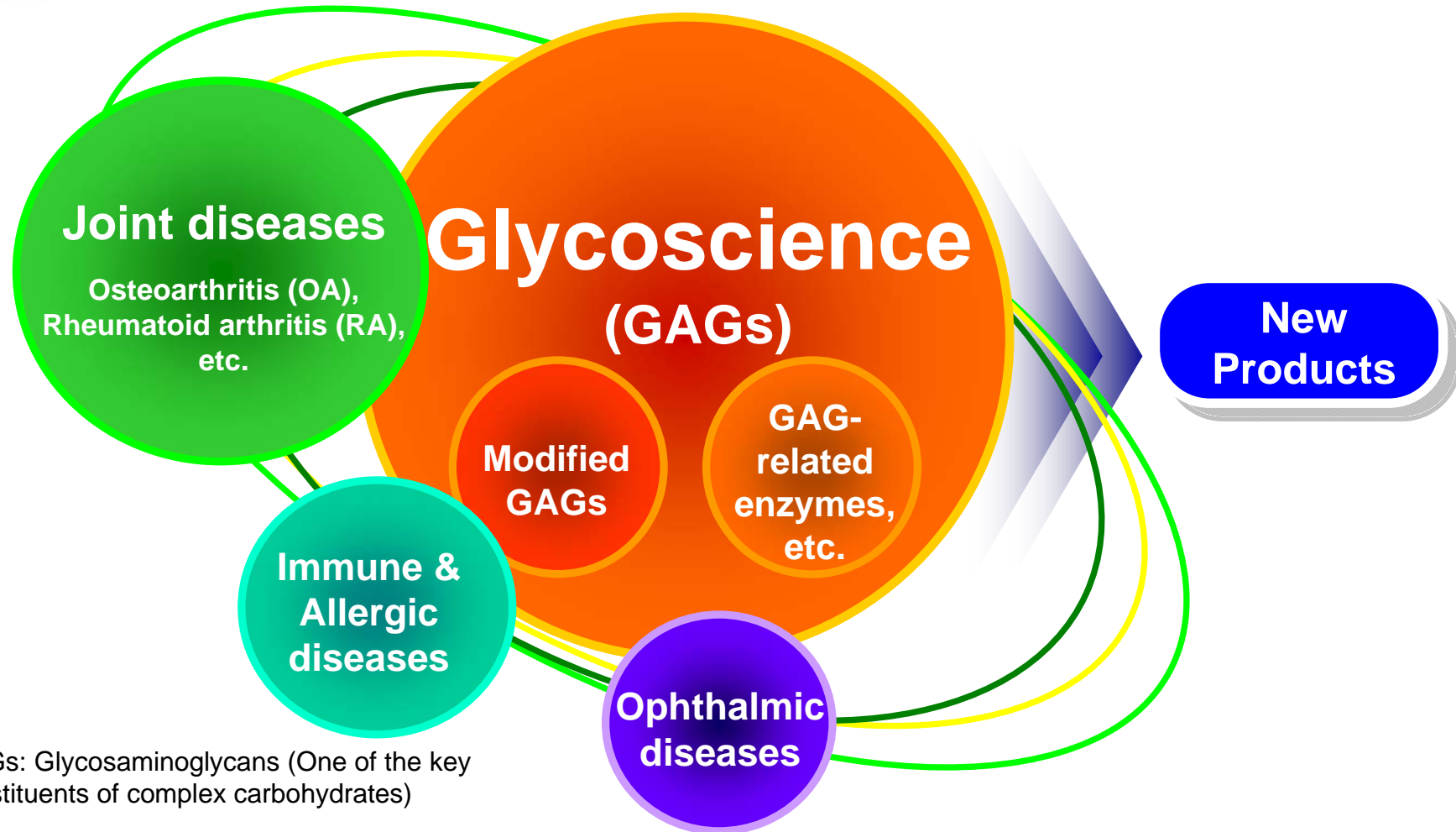
<<OPEGAN[®]>>: -1.8%

- Gradual recovery of market share
⇒ Forecasted 2H increase in sales volume due to intensification of sales promotion activities

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



Basic Policy on Research and Development



GAGs: 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	Applic ation	Appro val
Gel-One Cross-linked Hyaluronate	Knee Osteoarthritis	U.S.						
SI-6603 Condoliase*	Lumber Disk Herniation	Japan						
		U.S.						
SI-657 Hyaluronic Acid	Enthesopathy Additional indication for ARTZ	Japan						
SI-615 Adenosine A3 receptor agonist	Rheumatoid Arthritis	Japan						
SI-636 Anti-VAP-1 antibodies	Rheumatoid Arthritis, Inflammatory bowel syndrome	Japan						
	Ophthalmic product							
	Arthritic disorder Product							



SI-6603

- ◆ Substance : Condoliase
- ◆ Indication: Lumber disc herniation
- ◆ Method of use: Injection into lumber disc
(under X-ray observation)
- ◆ Current stage

Japan : P III

- Schedule

October 27, 2011: Submission of a PIII clinical trial notification to the PMDA

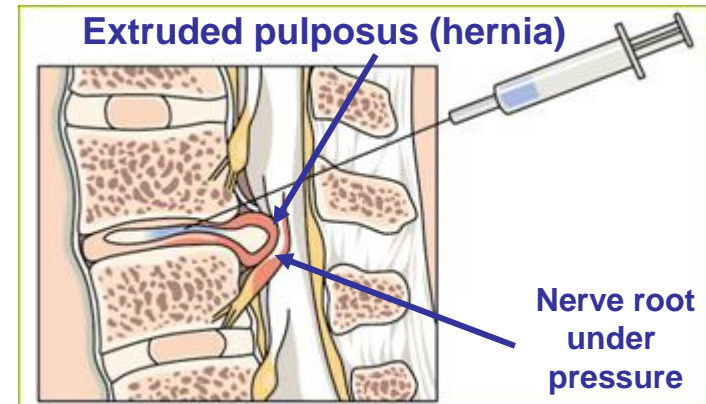
- Clinical Trial Summary

Examination of efficacy and safety in a randomized double-blinded comparative trial (against a placebo)

United States: PII

Completion of PII case registration in July 2011

Follow-up now underway





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

	FY2007	FY2008	FY2009	FY2010	FY2011 (Forecast)
Net Income per share	¥73.67	¥55.68	¥62.94	¥43.16	¥56.33
Annual Total Dividend	*¥30.00	¥25.00	¥25.00	¥25.00	¥25.00
Dividend Payout Ratio	40.7%	44.9%	39.7%	57.9%	44.4%

* 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 the future through powerful and sustainable action in the right direction

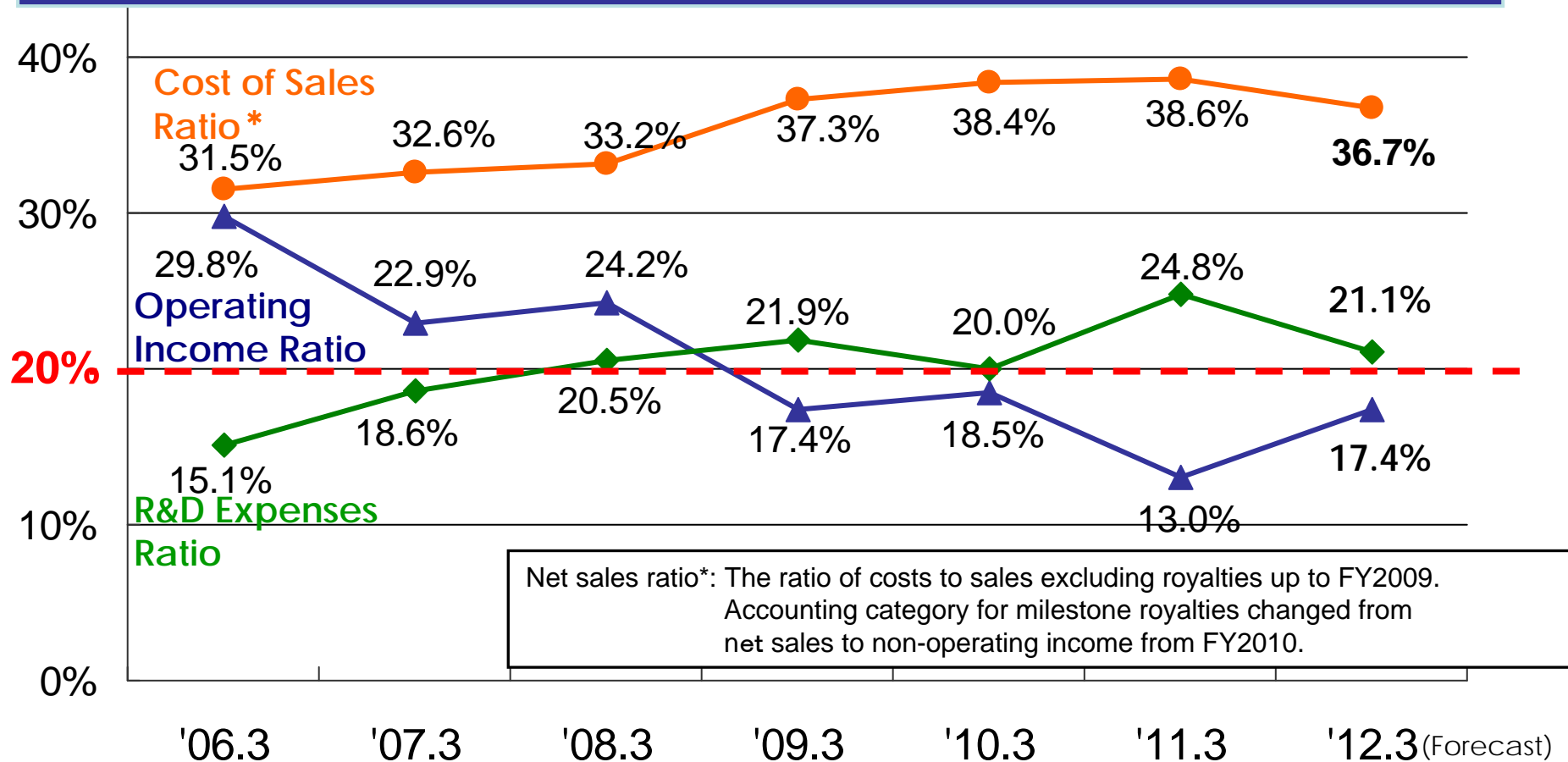
FY2011 Target: Net Sales ¥30.5 billion, Operating Income ¥6 billion

(Appendix)



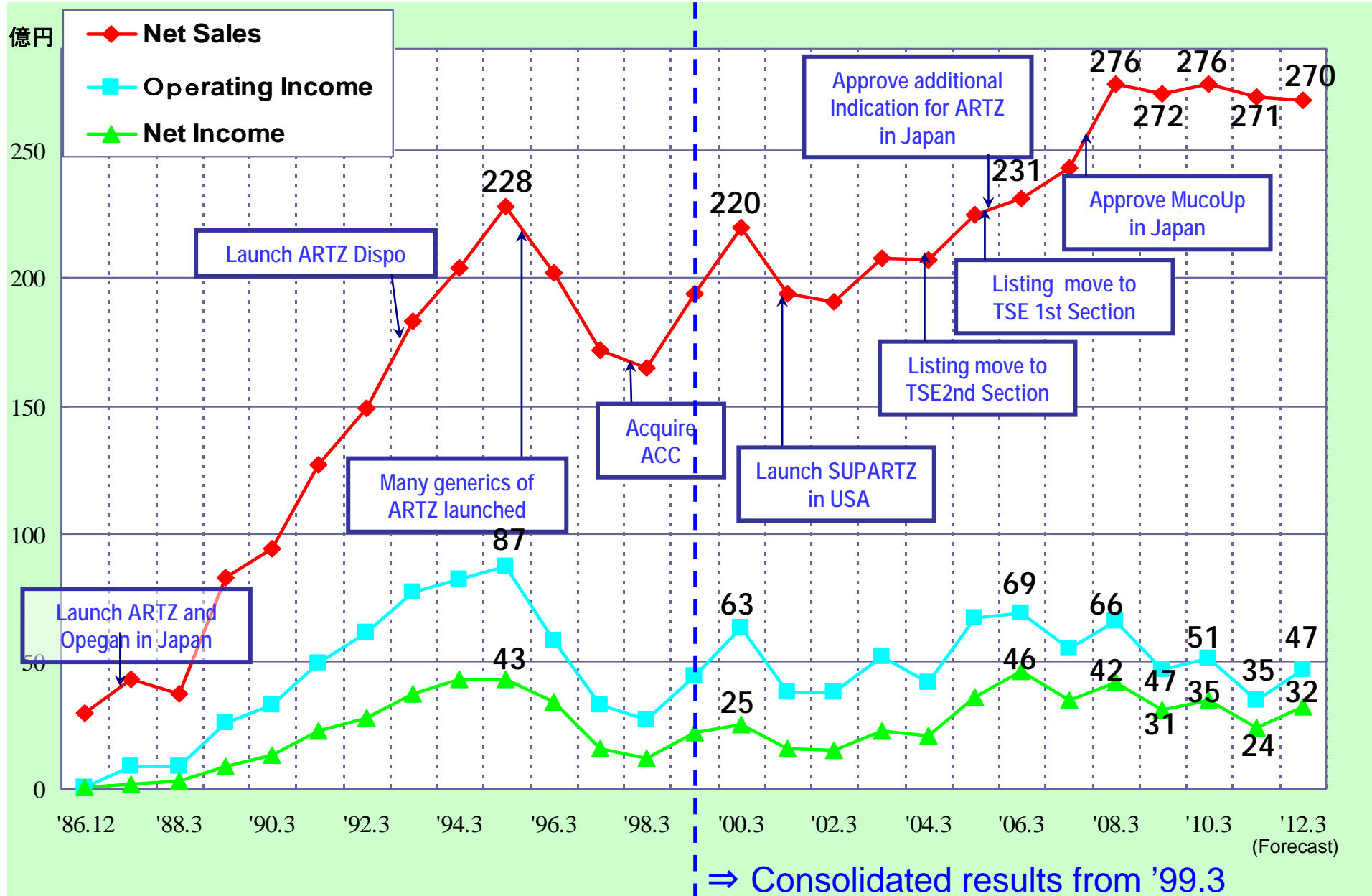
Trend in Financial Index

◆ **Point:** Depreciation of the new ARTZ Dispo production building began in FY 2008. Posting of Japanese clinical trial costs for SI-6603 was included in full in R&D expenses for FY 2010.





Business Progress & Highlights



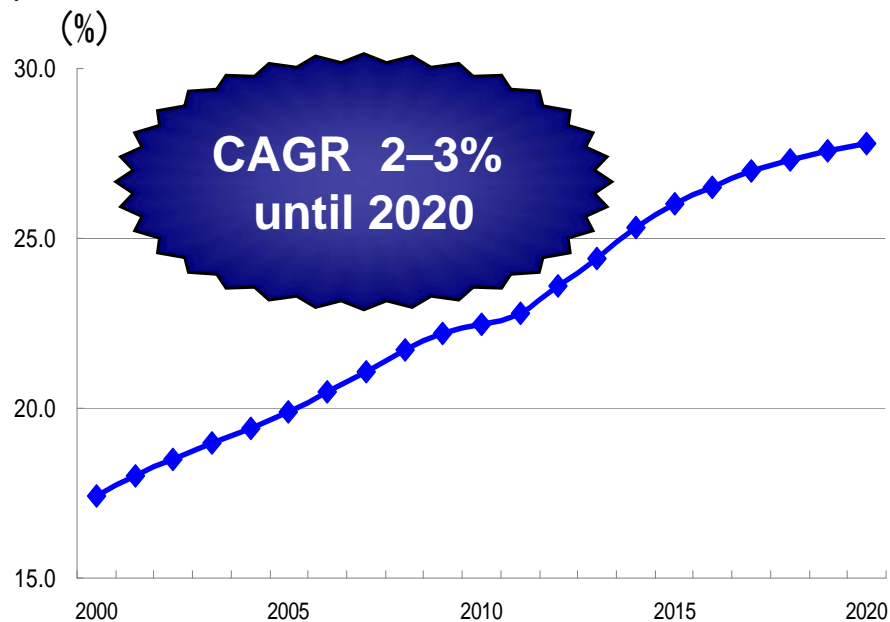


Expanding Market of ARTZ in Japan

- 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)

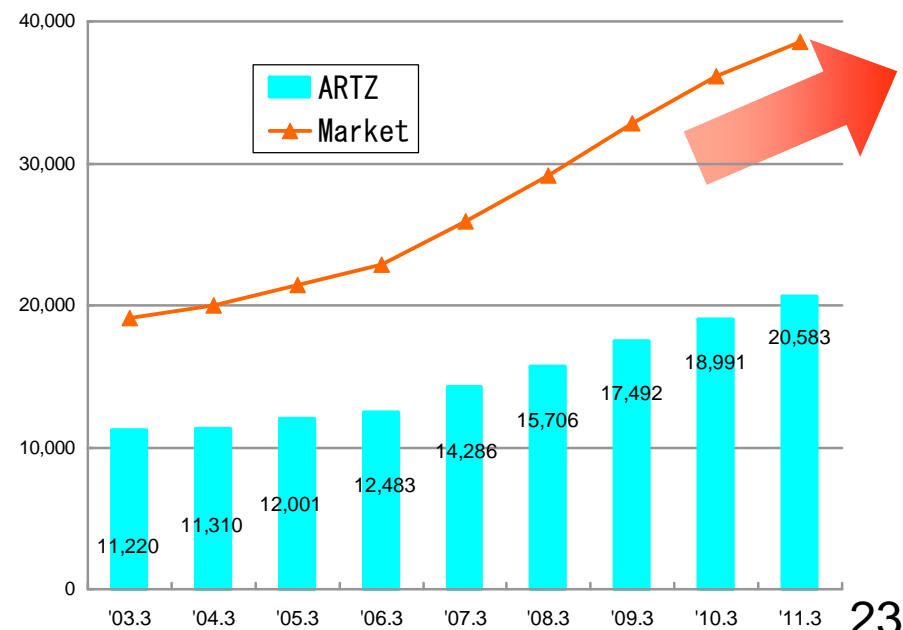
■ Growing Elderly Population (65 or over)

(Source: Ministry of Internal Affairs and Communications)



Deliveries of ARTZ to Medical Institutions (Japan)

(Thousand units)

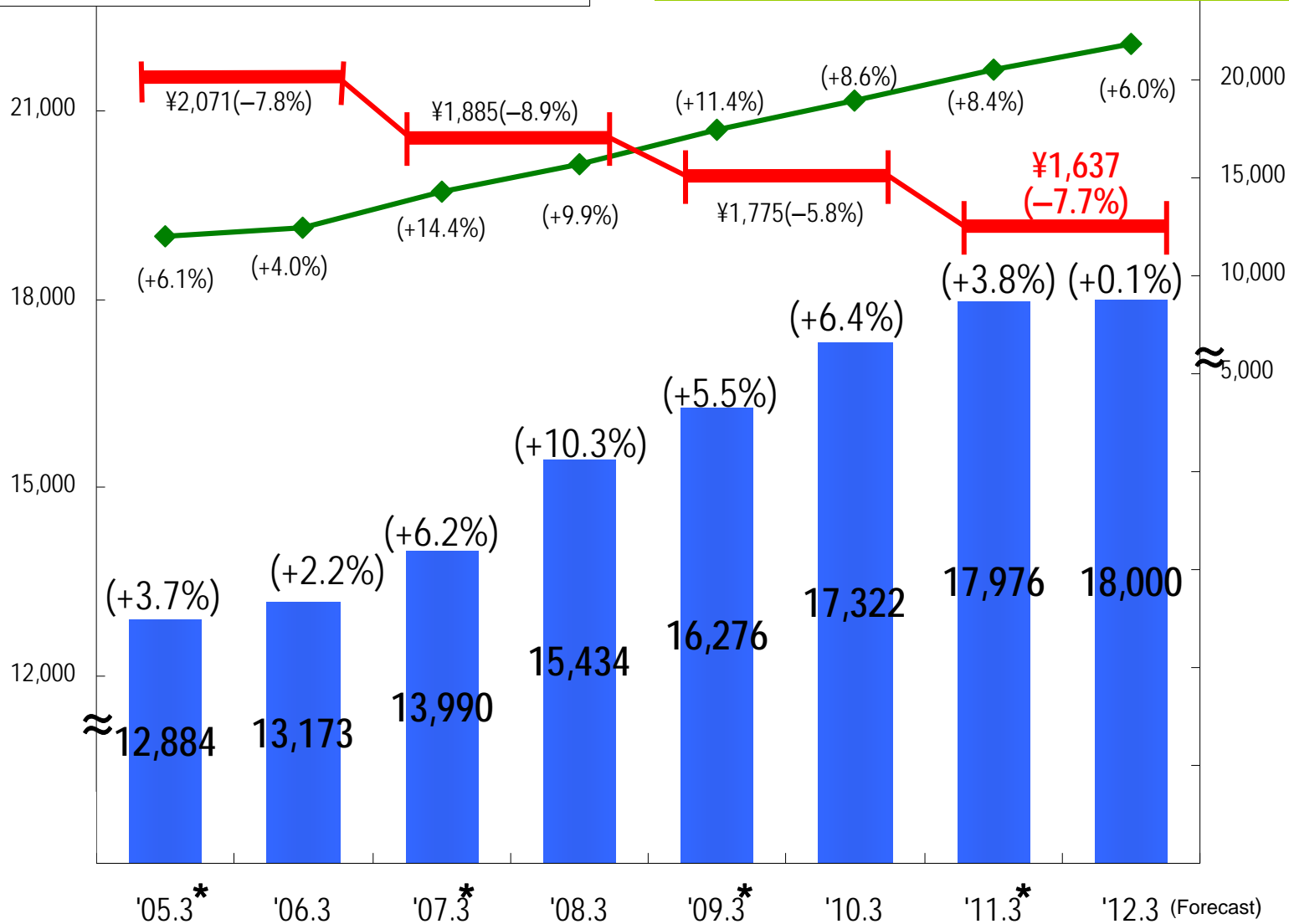




Trend in NHI Reimbursement Price and Our Domestic Pharmaceuticals Sales

- Japanese Pharmaceuticals Sales (Seikagaku)
- ARTZ Dispo NHI reimbursement price
- ◆ Deliveries of ARTZ to Medical Institutions

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



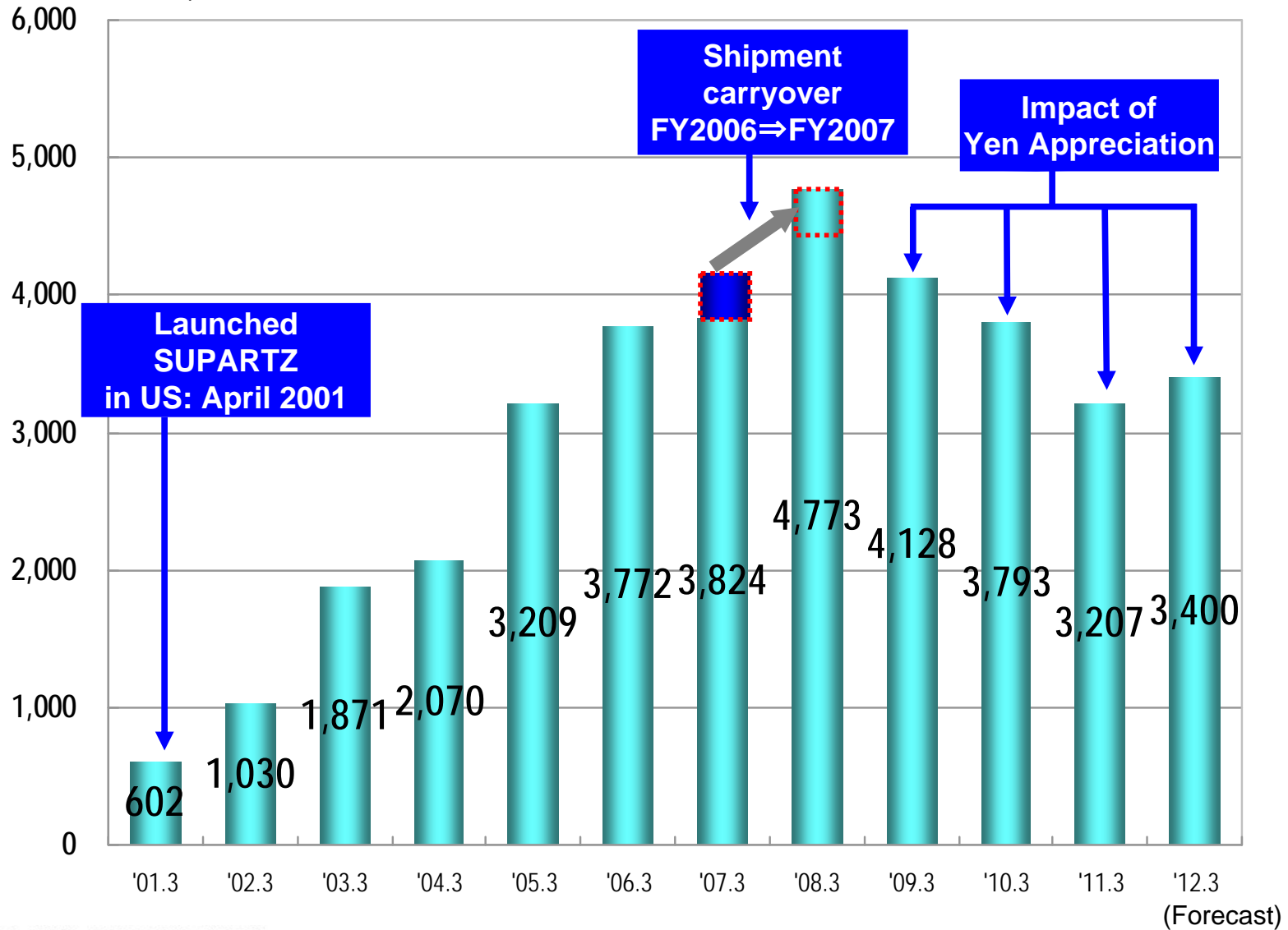
NHI price revision in FY2010
 Industry average: -6.3%
 Long-term listed items: additional 2.2% cut

*National Health Insurance Drug Revision



Trend in Hyaluronic Acid Products in Overseas Market

(Millions of Yen)

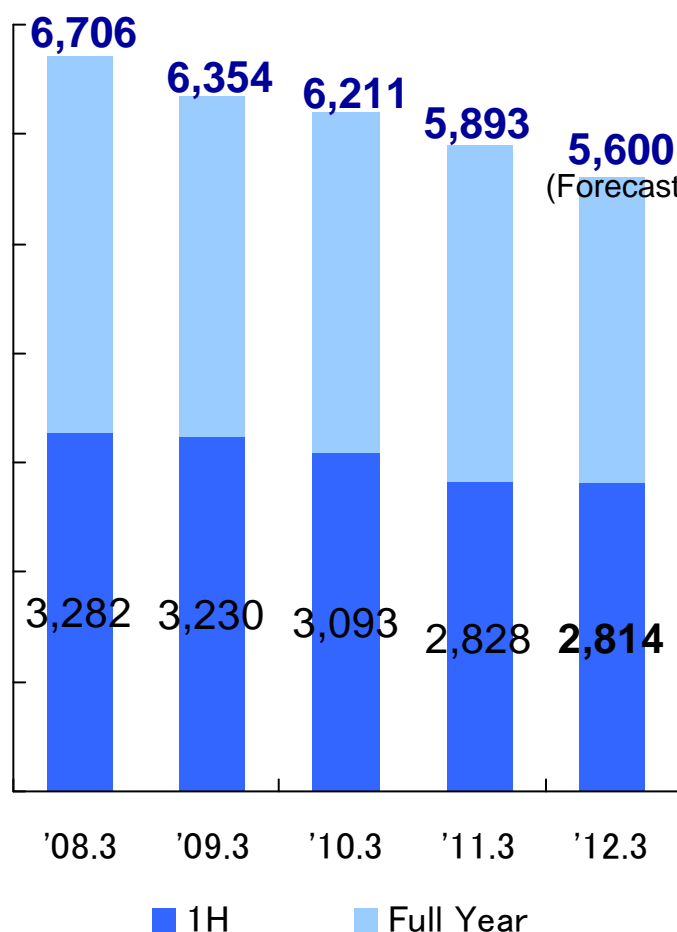




Sales of Fine Chemicals (value basis)

Sales of Fine Chemicals

(Millions of Yen)



■ ' FY2011 1H Results -0.5% (compared with 1H of FY2010)

<<Bulk Products>>: +6.8%

- Higher sales of hyaluronic acid owing to increased sales of products containing it

<<Research Reagents & Diagnostics>>: -2.5%

- Despite a sales increase at ACC, a sales decrease due to the impact of yen appreciation and the transfer of the diagnostic pharmaceuticals business

■ 2011 Full-year Forecasts -5.6% (year-on-year)

<<Bulk Products>>: +0.4%

- Sales of hyaluronic acid to remain strong

<<Research Reagents & Diagnostics>>: -8.0%

- Decrease due to the impact of yen appreciation and termination of the research reagents business, despite higher overseas sales



SI-657

◆ **Substance:** Hyaluronic acid (additional indication for ARTZ[®])

◆ **Indication:** Enthesopathy

*Four conditions: Lateral epicondylitis, patellar tendinitis, Achilles tendinitis, and plantar fasciitis

◆ **Development:** Joint development with Kaken Pharmaceutical

◆ **Estimated number of patients:**

Approx. 570,000 patients per year (total for four conditions)

◆ **Current stage:**

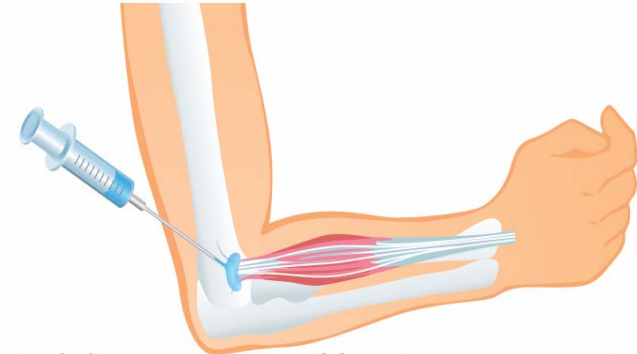
- **Phase II in Japan**

- **Schedule**

July 2011: Start of case registration for early PII study.

August 2011: Completion of case registration. Data currently being compiled.

Covers inflamed areas, penetrates tendons and ligaments, and provides pain relief efficacy



An inflammatory condition that can occur due to undue burden where tendons and ligaments bond to bone

◆ **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.
- The high viscoelasticity of hyaluronic acid results in residual presence at the site of administration, which enables long-term pain relief.



SI-615

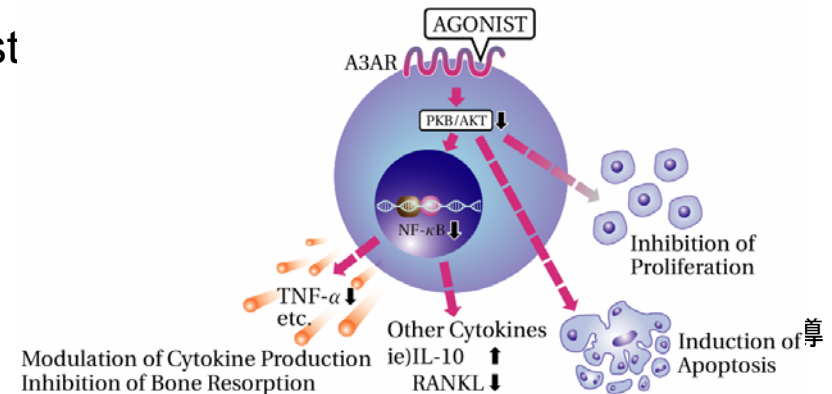
- ◆ **Substance:** Adenosine A3 receptor agonist
- ◆ **Indication:** Rheumatoid arthritis
- ◆ **Formulation:** Oral agent

【Current stage】

Phase I in Japan

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

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



◆ **Features:**

- In-licensed from CanFite BioPharma
- 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.



SI-636

◆ **Substance:** Anti-Vap-1 monoclonal antibodies

◆ **Indication:** Inflammatory diseases

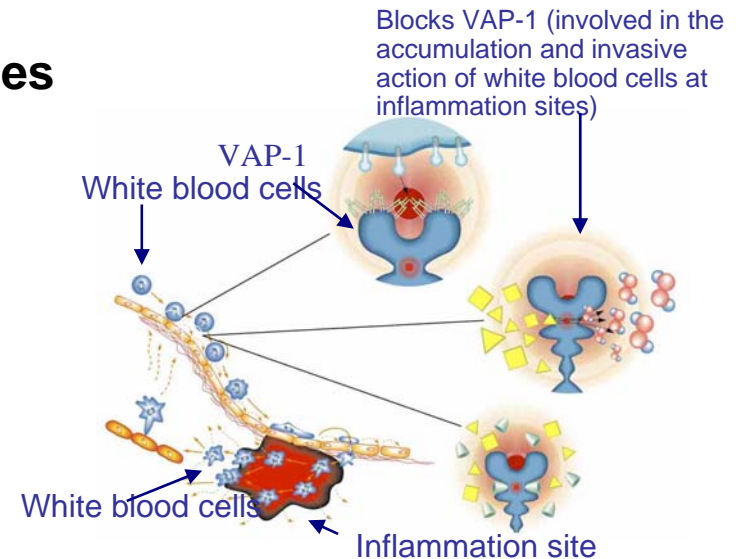
(Target disease: rheumatoid arthritis, psoriasis, Inflammatory bowel diseases)

◆ **Formulation:** Injectable solution

【Current Stage】

- Pre-clinical (Japan)
- Phase I in Europe, implemented by BioTie

⇒The licensor, BioTie, has completed PI repeat-dose trial for rheumatoid arthritis, 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:

- In-licensed from BioTie Therapies
- 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-636 uniquely acts on the adhesion molecules controlling leukocyte movement.



Change in Accounting Category for Royalties

The accounting category for income from royalties has been changed as follows, effective from the year ended March 2011.

Type of Royalties	Accounting Category	
	After Change	Before Change
Licensing Royalties Royalties relating to licensing of patents, etc.	net sales	net sales
Milestone Royalties Royalties designed to allow the early recovery of R&D expenses as each milestone is reached on the path from production development to Marketing	Non-operating income	

Reasons for change:

It was judged that the presentation of income from milestone royalties as non-operating income would more clearly represent the results of operating activities.



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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