

Financial Results for the First Half of Fiscal Year 2013 (April 1, 2013 – September 30, 2013)

Exploring the Innovative Promise of Glycoscience



<http://www.ehiza.jp>



SEIKAGAKU CORPORATION

(TSE:4548)

Financial Results for 1H of Fiscal 2013

(Millions of Yen)

	FY2013 1H Results	FY2012 1H Results	vs. FY12/1H Results	Initial Forecast for 1H (5/10)	vs. Initial Forecast for 1H
Net Sales	15,405	13,239	+2,166 (+16.4%)	15,200	+205 (+1.3%)
Operating Income	3,488	1,324	+2,163 (+163.3%)	2,700	+788 (+29.2%)
Ordinary Income	3,783	1,781	+2,002 (+112.4%)	2,950	+833 (+28.3%)
Net Income	3,118	1,266	+1,852 (+146.3%)	2,450	+668 (+27.3%)
R&D Expenses	3,068	3,412	-343 (-10.1%)	3,300	-231 (-7.0%)
R&D Expenses Ratio (to Net Sales)	19.9%	25.8%	-5.9pt	21.7%	-1.8pt
Net Income Per Share	¥54.90	¥22.29	+¥32.61	¥43.13	+¥11.77

Average Exchange
Rate (1US\$)

¥98.86

¥79.42

¥95.00

Net Sales for 1H of FY2013 (year-on-year)

Net sales: ¥15,405 (+¥2,166 / +16.4%)

(Millions of Yen)

【Pharmaceuticals: ¥13,315 (+¥1,862)】

- Japan (+¥168)

- ARTZ[®]: Higher deliveries to medical institutions, but lower growth rate
Seikagaku sales slightly up due to inventory adjustment by sales partner
- OPEGAN[®]: Share decrease due to continued intense competition, despite slightly higher deliveries to medical institutions
Seikagaku sales up due to rebound from lower shipments of the same period of fiscal 2012
- MucoUp[®]: Seikagaku sales up due to successful measures to penetrate endoscopic surgery

- Overseas (+¥1,477)

- ARTZ[®]: - U.S.; Slightly lower local sales of SUPARTZ. Seikagaku sales up due to factors including the impact of yen depreciation
- China; Continuing increase in local sales
- Gel-One[®]: Higher sales on progress with measures to establish distribution channels

- Bulk Products (+¥216): Increase in sales of hyaluronic acid

【LAL: ¥2,089 (+¥303)】 Increase in overseas sales and the impact of yen depreciation

*Impact of yen depreciation on net sales: (+760)

■ Increase in sales due to higher volumes of overseas pharmaceuticals such as Gel-One and the impact of yen depreciation

Income for 1H of FY2013 (year-on-year)

(Millions of Yen)

Operating Income: ¥3,488 (+¥2,163 / +163.3%)

【Cost of Sales (+¥636)】

* Cost of sales ratio: 35.5% (-1.0pt)

- Improvement in the cost of sales ratio due to increase in overseas pharmaceuticals sales volumes and the impact of yen depreciation

【SG&A expenses (-¥634)】

- R&D expenses: ¥3,068 (-¥343): Decrease in depreciation and other indirect costs
- Decrease in Gel-One lawsuit expenses

*Impact on income of change in depreciation method (declining-balance method ⇒ straight-line method): (about + ¥170)

Net Income: ¥3,118 (+¥1,852 / +146.3%)

【Non-Operating Income/Expenses (-¥160)】

- Non-recurrence of royalty income recorded in the previous year (-¥428)
- Impact of yen depreciation on valuation of foreign currency-denominated financial assets and securities (+¥257)

【Extraordinary Incomes/losses (+¥49)】

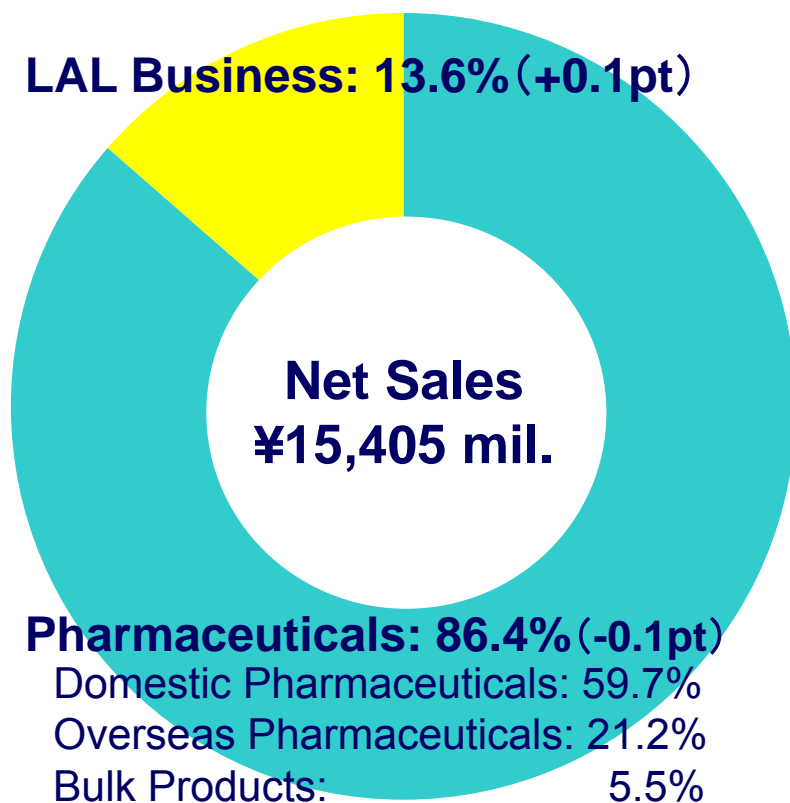
- Recording of an extraordinary gain on the sale of investment securities (+¥560)
- Recording of an extraordinary loss on costs associated with integration of the Kurihama Plant, etc. (-¥510)

*Decrease in tax expense from application of preferential taxation due to designation of the Takahagi Plant as a special district for industrial revitalization

- Sharp increase in operating income due to higher gross profit and lower SG&A expenses
- Sharp increase in net income due in part to an extraordinary gain on the sale of investment securities, despite an extraordinary loss on costs associated with integration of the Kurihama Plant, etc.

Net Sales by Business Segment (1H of FY2013)

(Millions of Yen)



Segment	Net Sales	vs. Previous Period	Change
[Pharmaceuticals]	13,315	+1,862	+16.3%
Domestic Pharmaceuticals	9,201	+168	+1.9%
Overseas Pharmaceuticals	3,261	+1,477	+82.8%
Bulk Products	852	+216	+34.0%
[LAL Business]	2,089	+303	+17.0%
Total	15,405	+2,166	+16.4%
(Overseas Sales)	4,764	+1,808	+61.2%



0% 25% 50% 75% 100%

Results for 1H of FY2013 (Compared with Initial Forecast)

(Millions of Yen)

Net Sales: ¥15,405 (+¥205 / +1.3%)

- Pharmaceuticals(+¥215): Higher sales volumes of overseas pharmaceuticals and bulk products compensated for underperformance of domestic pharmaceuticals

Operating Income: ¥3,488 (+¥788 / +29.2%)

- Cost of sales (about -¥150): Decrease due to lower sales volumes
- SG&A expenses (about -¥400): R&D expenses (-¥231; forecast: ¥3,300 ⇒ actual: ¥3,068)
Decrease in other SG&A expenses

Net Income: ¥3,118 (+¥668 / +27.3%)

- Increase in non-operating income: Increase in foreign exchange gains related to valuation of foreign currency-denominated financial assets and securities, reflecting the impact of yen depreciation
- Occurrence of extraordinary gains and losses: gain on the sale of investment securities (+¥560) and costs associated with integration of the Kurihama Plant, etc. (-¥510)

■ Sales slightly higher than expected. Income higher than expected due to a decrease in SG&A expenses, such as R&D expenses, and higher foreign exchange gains on foreign currency-denominated financial assets and securities, reflecting the impact of yen depreciation.

Revised Forecast for FY2013

(Millions of Yen)

	FY2013 Revised Forecast	Initial Forecast	vs. Initial Forecast	FY2012 Results	vs. Previous Year
Net Sales	30,200	29,900	+300 (+1.0%)	26,639	+3,560 (+13.4%)
Operating Income	4,800	4,550	+250 (+5.5%)	3,126	+1,673 (+53.5%)
Ordinary Income	5,500	5,000	+500 (+10.0%)	4,302	+1,197 (+27.8%)
Net Income	4,450	4,050	+400 (+9.9%)	3,256	+1,193 (+36.6%)
R&D Expenses	6,900	7,050	-150 (-2.1%)	6,838	+61 (+0.9%)
R&D Expenses Ratio (to Net Sales)	22.8%	23.6%	-0.8pt	25.7%	-2.9pt
Net Income Per Share	¥78.34	¥71.29	+¥7.05	¥57.33	+¥21.01

Average Exchange Rate
(¥/1US\$)

¥97.00
(2H forecast)

¥95.00

¥83.11

Revised Forecast for FY 2013 (Comparison with the initial forecast)

(Millions of Yen)

Net sales: ¥30,200 (+¥300 / +1.0%)

- Domestic Pharmaceuticals (approx. -¥450): Weak deliveries of ARTZ to medical institutions
- Overseas Pharmaceuticals (approx. +¥700): Higher shipments of SUPARTZ in the U.S. and Gel-One and the impact of yen depreciation
- Bulk Products (approx. +¥50): Sales increase in hyaluronic acid despite of decrease in chondroitin sulfate

*Impact of yen depreciation on net sales: about +300

Operating income: ¥4,800 (+¥250 / +5.5%)

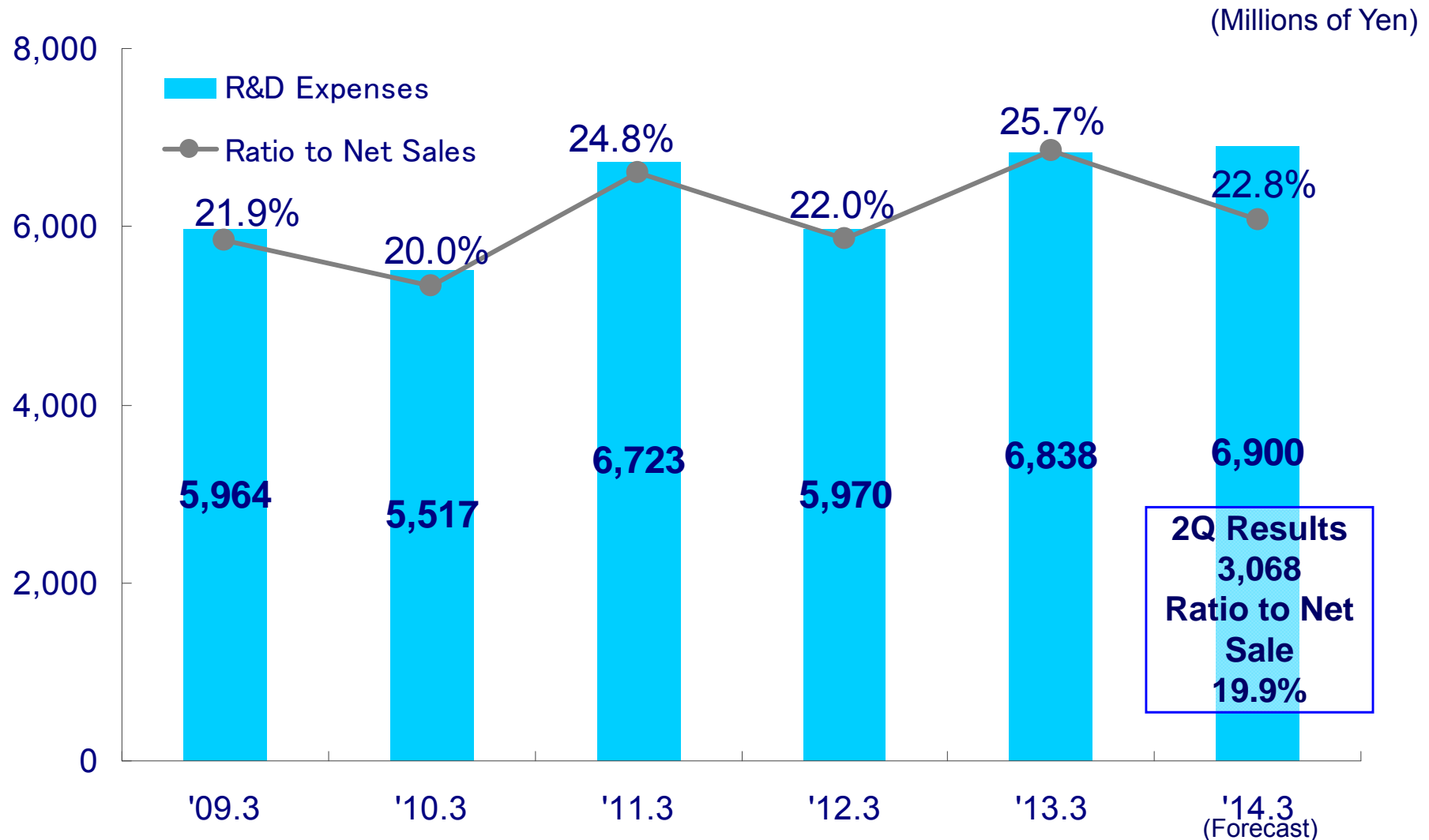
- Cost of sales (about +¥200): Accelerated start of depreciation of new Gel-One production facilities
- SG&A expenses (about -¥150): Decrease in R&D expenses (¥7,050 → ¥6,900)
Other SG&A expenses nearly in line with forecast

Net income: ¥4,450 (+¥400 / +9.9%)

- Increase in non-operating income: Increase in foreign exchange gains related to valuation of foreign currency-denominated financial assets and securities, reflecting the impact of yen depreciation

■ Slightly higher sales on higher shipments of SUPARTZ in the U.S. and Gel-One and the impact of yen depreciation, despite lower sales of domestic pharmaceuticals. Upward revision of the income forecast due to factors including lower R&D expenses and higher non-operating income.

Trend in R&D Expenses and Ratio to Net Sales

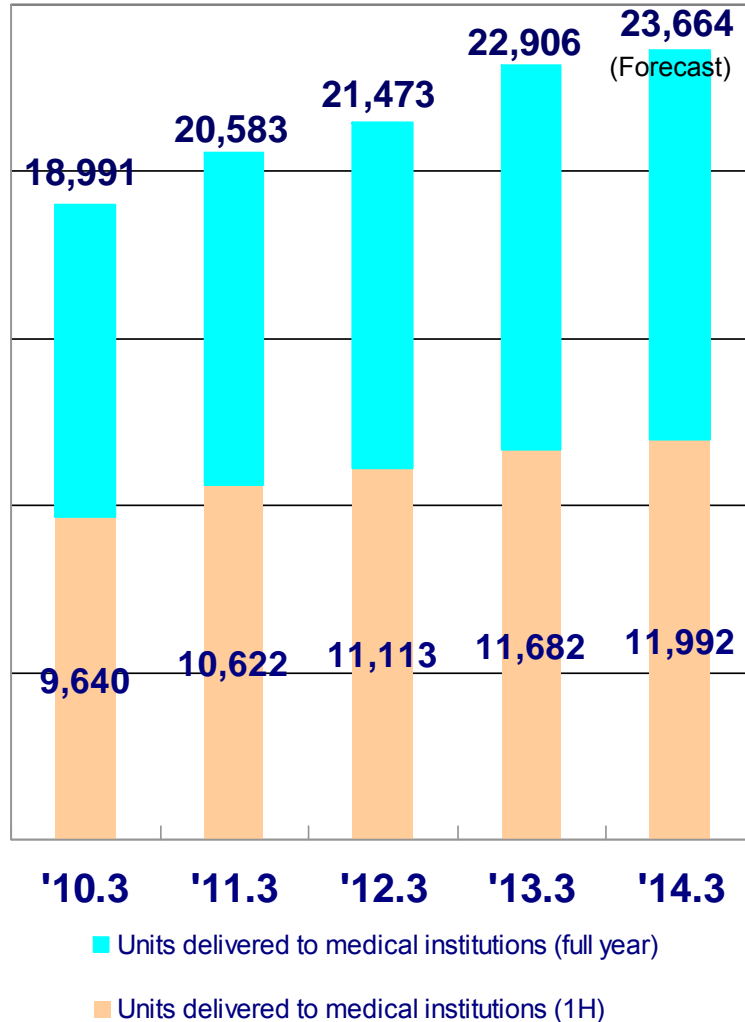


R&D expenses for FY2013 at a high level due to progress with development themes such as SI-6603 in Japan and the U.S.

Domestic Sales of ARTZ[®] (unit deliveries to medical institutions/ year-on-year)

ARTZ[®] Deliveries to Medical Institutions

(Thousand Units)



FY2013 1H Results

<<Market>>: +0.5%

<<ARTZ[®]>>: +2.6%

- Enhanced brand reputation as the original product
- Impact of introduction of a plastic syringe product

⇒ ARTZ drives the market

Market share: 56.7% (+1.2 pt.)

FY2013 Forecast

<<ARTZ[®]>>: +3.3%

- Continuous implementation of disease awareness campaigns
- Promote marketing activities that take advantage of brand reputation
- Extend medical specialties on departments other than orthopedic surgery

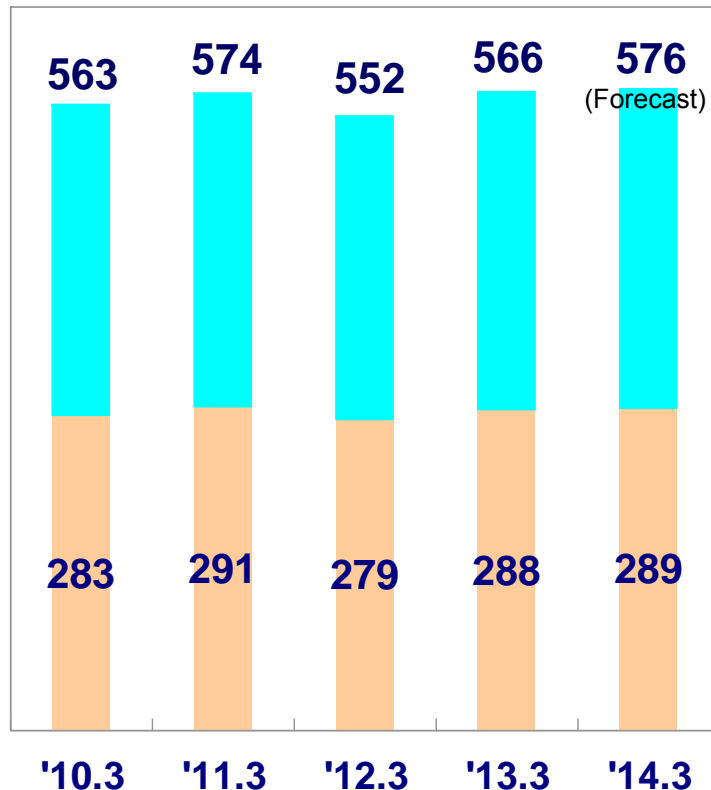
⇒ Aim to outpace market growth

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

Sales of OPEGAN[®] (unit deliveries to medical institutions /year-on-year)

OPEGAN[®] deliveries to Medical Institutions

(Thousand Units)



■ Units delivered to medical institutions (full year)

■ Units delivered to medical institutions (1H)

■ FY2013 1H Results

<<Market>>: **+3.0%**

<<OPEGAN[®]>>: **+0.4%**

- Only a slight increase in deliveries to medical institutions amid continued fierce competition
- Market share declined

■ FY2013 Forecast

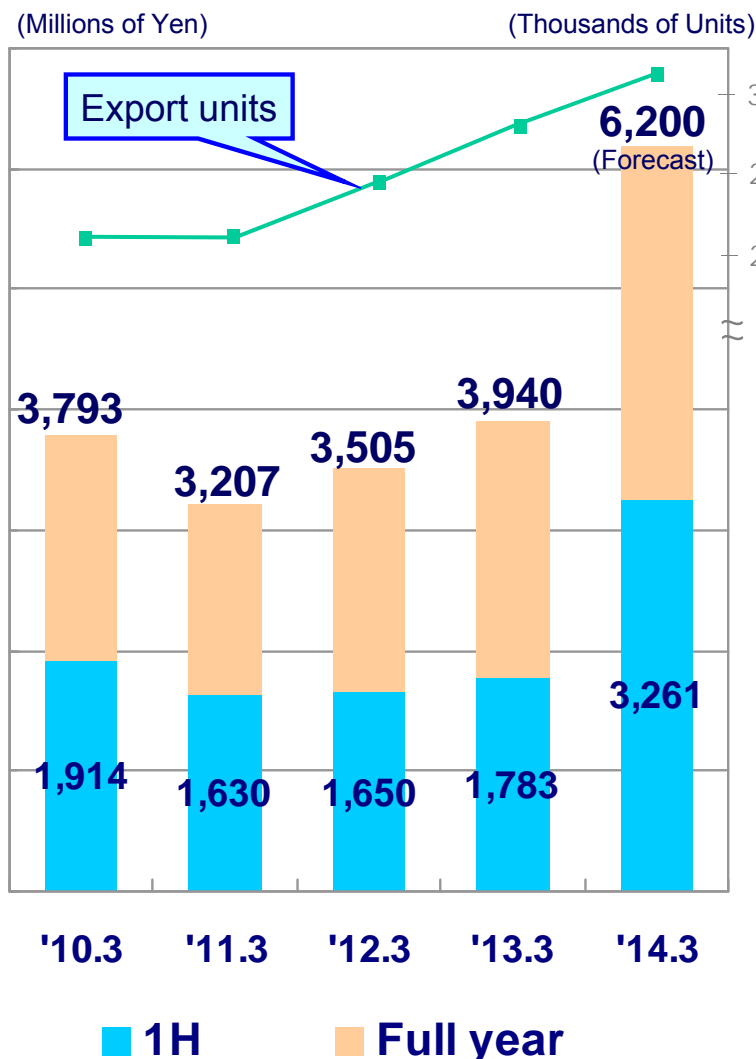
<<OPEGAN[®]>>: **+1.7%**

- Implementation of measures to boost sales activities together with sales partner
- ⇒ Aim for an increase in deliveries to medical institutions in the second half

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

Overseas Pharmaceuticals (value basis/ year-on-year)

Overseas Pharmaceuticals Sales



■ FY2013 1H Results: ¥3,261 million (+82.8%)

(Impact of yen depreciation: about +¥500 million)

- <<ARTZ (multiple injection)>>: +40.9% (Seikagaku export sales)
- ◆ SUPARTZ in the U.S.: Only a slight decrease in local sales as reimbursement restriction by some insurance companies ran its course
- ◆ ARTZ in China: Steady development of local sales
- ◆ Seikagaku export sales: Increase on yen depreciation and local inventory build-up
- <<Gel-One (single injection)>>
- ◆ Large increase in both local sales and Seikagaku export sales

■ FY2013 Forecast: ¥6,200 million (+57.3%)

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

- <<ARTZ (multiple injection)>>: +24.2% (Seikagaku export sales)
- ◆ SUPARTZ in the U.S.: Aim to recapture share through active sales promotion activities directed at a broader target
- ◆ ARTZ in China: Continued excellent reputation for high quality and proven performance
- ◆ Seikagaku export sales: Increase in shipments due to yen depreciation and higher local sales
- <<Gel-One>>
- ◆ Increase in Seikagaku exports from sales channel expansion measures

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

■ Gel-One sales measures

- ◆ Progress made in contracts with major pharmaceutical distributors
- ◆ Progress in negotiations with insurance companies, too
- ◆ Implementation of measures to increase physician awareness of Gel-One
- ◆ Start of labeling change (addition) clinical trial in the U.S.
 - Implemented as a measure to further increase product value
 - Trial initiated in August 2013



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



< Gel-One® pamphlet >

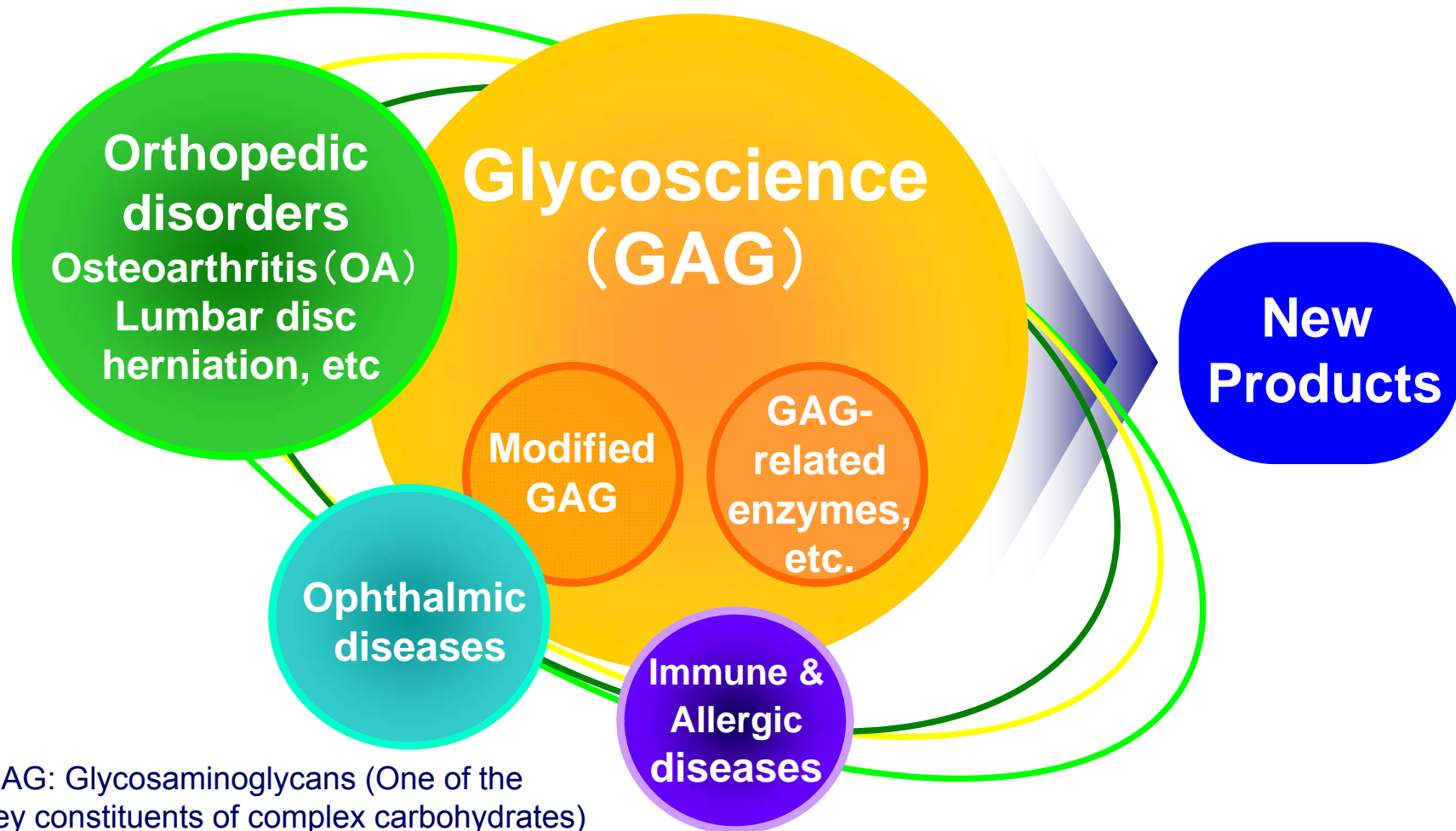
■ Gel-One dedicated production facilities

- ◆ Newly built within the No. 3 Production Building of the Takahagi Plant (investment: ¥3.2 billion)
- ◆ Production capacity that can cope with medium- to long-term sales expansion



< Gel-One® new formulation facilities >

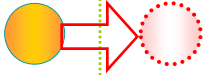





Basic Policy on Research and Development



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

■ 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	P I	P II	P III	Appli- cation
SI-6603 Condoliase	Lumbar Disk Herniation	Japan			 NDA submission planned in FY2013	
		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

- Reduces nerve pressure and alleviates pain by shrinking herniation
- Favorable results from Japan Phase III in August 2013

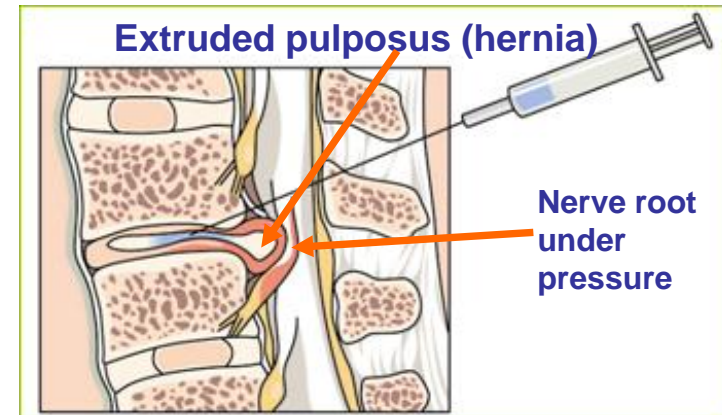
- **Substance:** Condoliase
- **Indication:** Lumbar disc herniation
- **Method of use:**
Injection into lumbar disc
(under X-ray observation)
- **Current stage:**

Japan: PIII

- ◆ Obtained favorable results
Aim for an NDA in FY2013

U.S.: PIII

- ◆ Case registration started in October 2013



◆ Features:

- Pain alleviated by reducing hernia-related nerve pressure through the specific degradation of GAGs (chondroitin sulfate, etc.), which are the main components of the nucleus pulposus
- No breakdown of proteins, so no effect on other tissues (blood vessels, nerves, etc.)
- Single-injection treatment with SI-6603 expected to become an alternative to surgery
- Seikagaku concluded an exclusive distributorship agreement in Japan with Kaken Pharmaceutical Co., Ltd.

SI-657 Outline

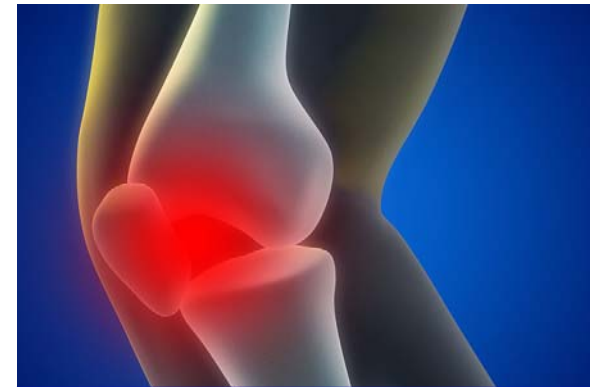
- Exerts an inhibitory action to improve symptoms of enthesopathy
- Japan Phase III trial started in May 2013 making steady progress
- **Substance:** Hyaluronic acid (additional indication for ARTZ[®])
- **Indication:** Enthesopathy (targets; four conditions)
- **Development:** Joint development with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



- Lateral epicondylitis (tennis elbow)



- Achilles tendinitis
- plantar fasciitis



- patellar tendinitis (jumper's knee)

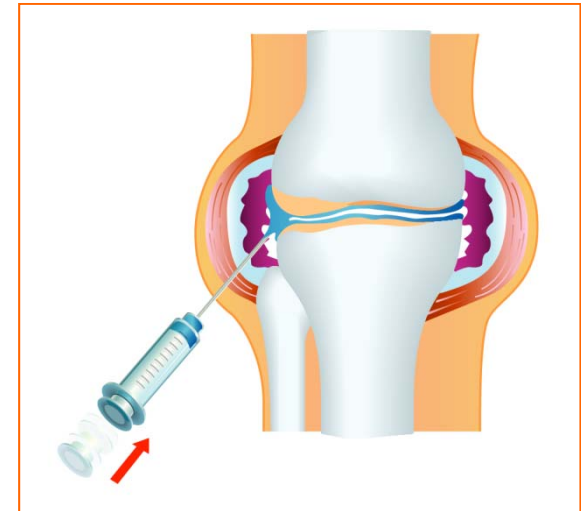
Estimated annual number of patients (total for four conditions) : About 570,000

The aim is to contribute to symptom improvement in more patients by further increasing the added value of ARTZ.

SI-613 Outline

- Prompt and long-term relief of severe pain and inflammation associated with knee osteoarthritis
- Global development including the U.S. and other areas

- **Substance:** SI-613
(Hyaluronic acid-NSAID*¹ conjugates)
- **Indication:** Knee OA
- **Formulation:** Injection into knee joint
- **Current stage:** **Japan: PII**
 - ◆ March 2013: Case registration started
 - ◆ August 2013: Case registration completed



- ◆ **Features:**
 - Hyaluronic acid combined with NSAID for relief of severe pain and inflammation of OA using Seikagaku's unique technology
 - Sustained-release*² of the NSAID for long-term improvement of severe pain and inflammation
 - Minimal side effects compared to oral or topical treatment of the NSAID

*1 NSAID: Non-Steroidal Anti-Inflammatory Drug

*2 Sustained release: Gradual release of active ingredients to produce a sustained therapeutic effect over a long period

SI-614 Outline

- Improves symptoms of dry eye by protecting the ocular surface and promoting corneal epithelial wound healing
- Next clinical trial under consideration after U.S. Phase II

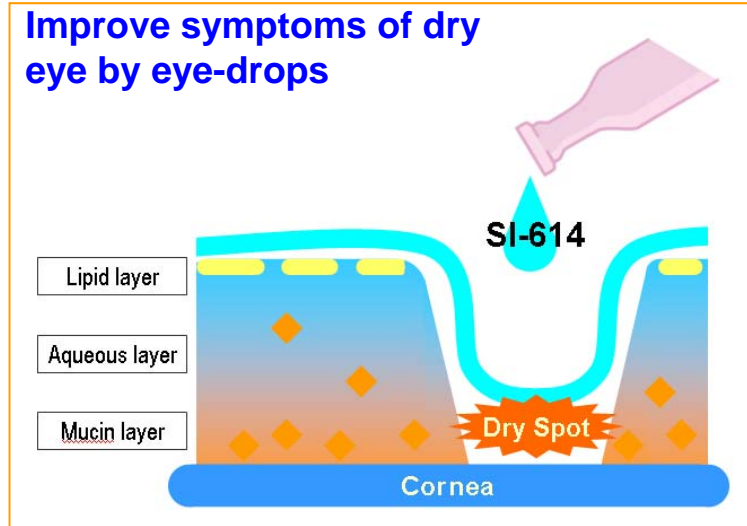
- Substance: SI-614 (Modified Hyaluronate)
- Indication: Dry eye
- Formulation: Ophthalmic solution
- Current Stage :

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 protecting the ocular surface and promoting corneal epithelial wound healing in dry eye patients.
- Although Dry eye is a multifactorial disease, only an anti-inflammatory drug is available in the U.S. currently. SI-614 will provide a new alternative to the treatment of dry eye through the promising mode of action.



Basic Policy on Profit Distribution

◆ Dividends

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

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

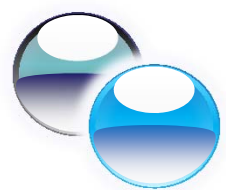
◆ Internal Reserve

Appropriated for R&D, and capital investment, etc., in accordance with medium-to-long term perspective

◆ Flexible Capital Policy

Share buy-back is an option for improving capital efficiency

	FY2009	FY2010	FY2011	FY2012	FY2013 (Forecast)
Net Income per share	¥62.94	¥43.16	¥57.58	¥57.33	¥78.34
Annual Total Dividend	¥25.00	¥25.00	¥25.00	¥25.00	¥26.00
Dividend Payout Ratio	39.7%	57.9%	43.4%	43.6%	33.2%



Appendix

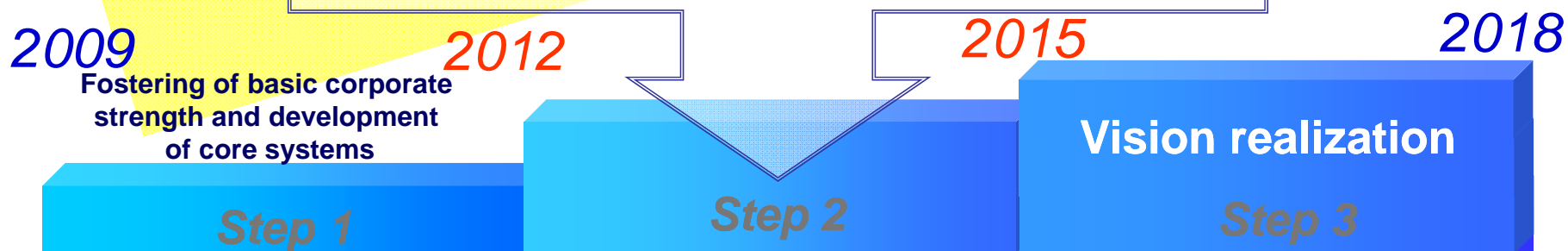
Ten-Year Vision and Mid-term Management Plan

Ten-Year Vision “Global Category Pharma”

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

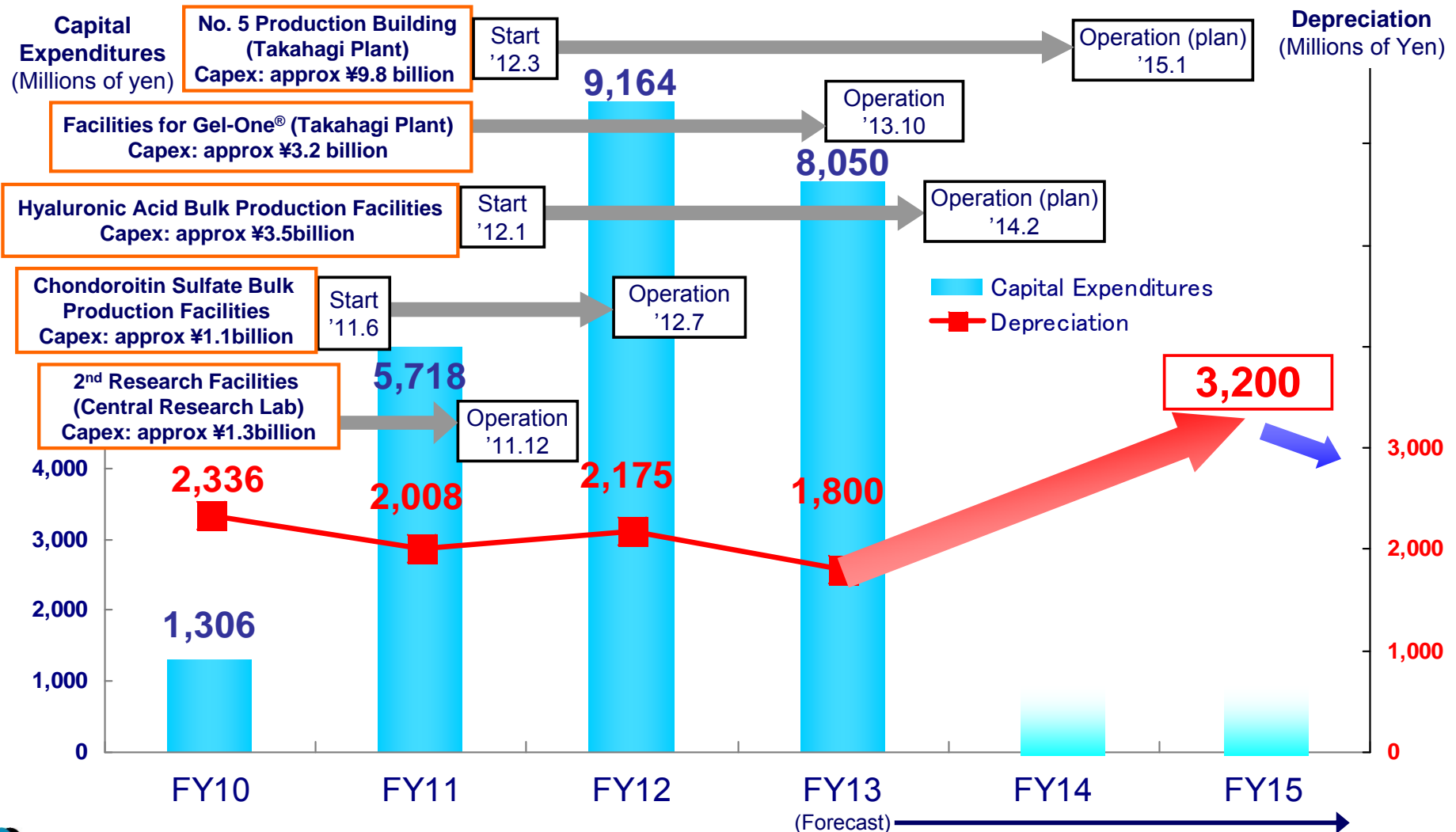
ACT for the future
Advance · Challenge · Transparency

**Cultivation of new leads
for Achieving the Ten-Year Vision**

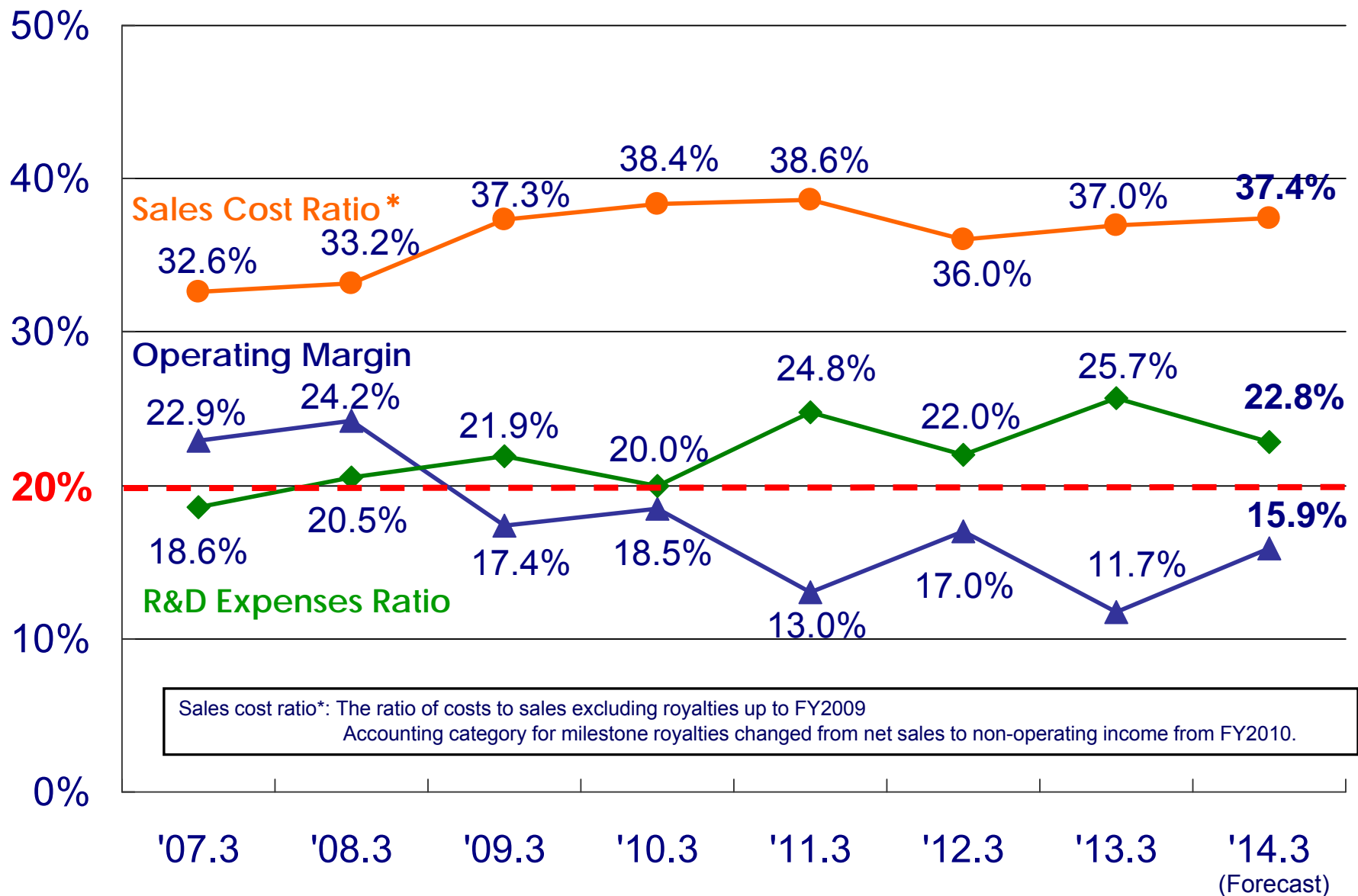


Mid-term Management Plan: Trend in Capital Expenditures and Depreciation

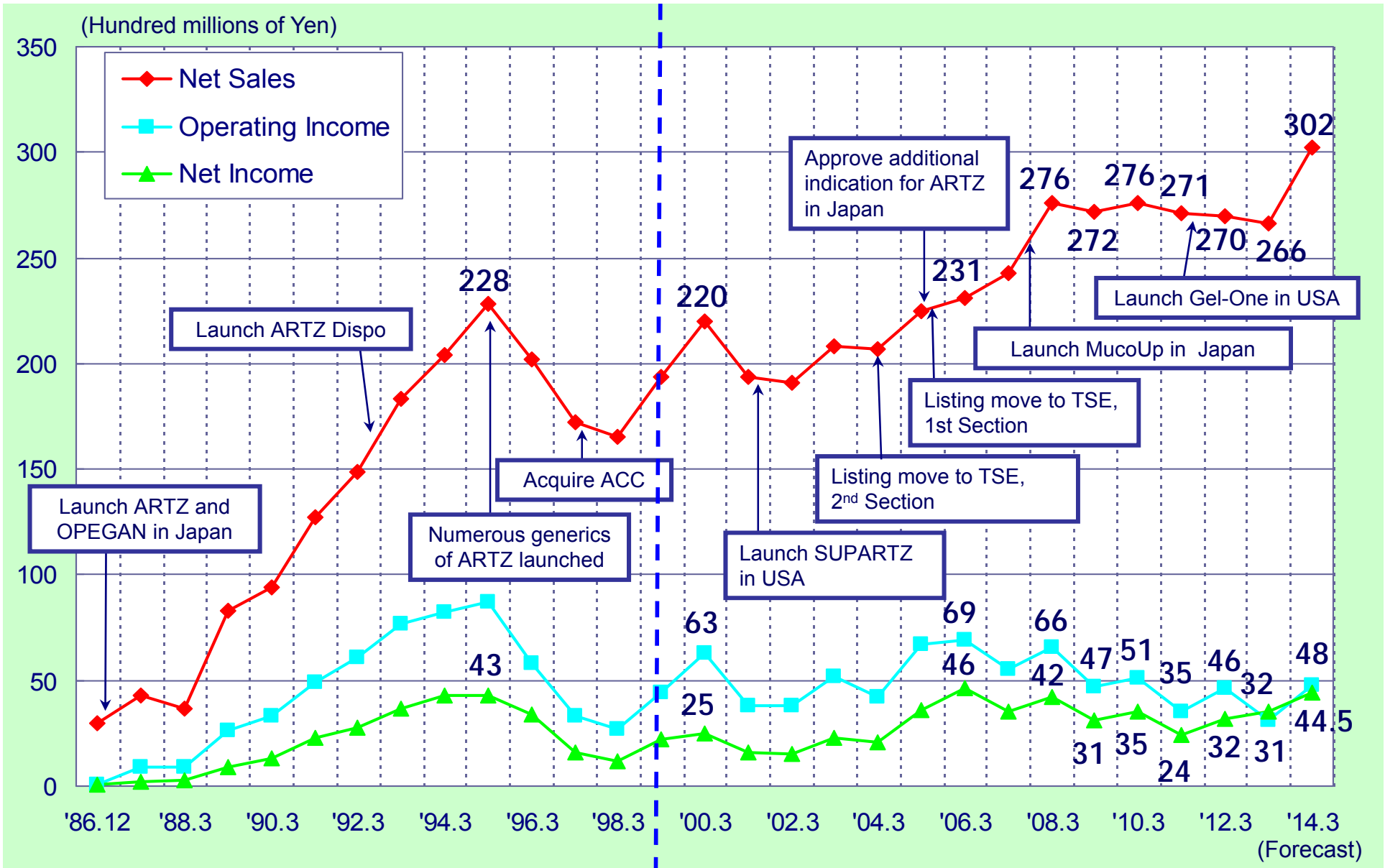
- Depreciation will increase due to implementing large and active capital expenditures
- Peak figures will be decreased from ¥3.5 billion to ¥3.2 billion by the change of the depreciation method



Trend in Financial Index



Business Progress & Highlights

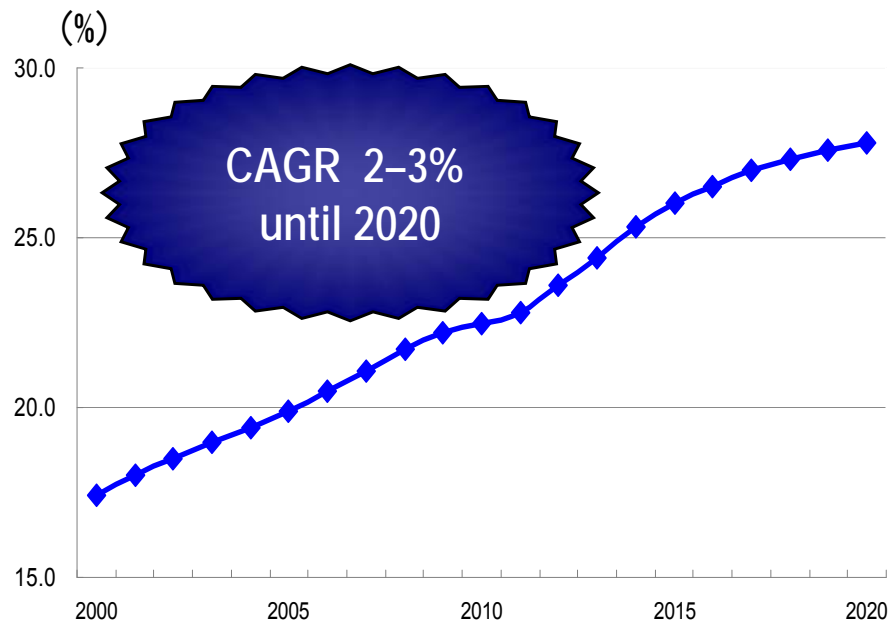


Expanding Market of ARTZ® in Japan

- 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)

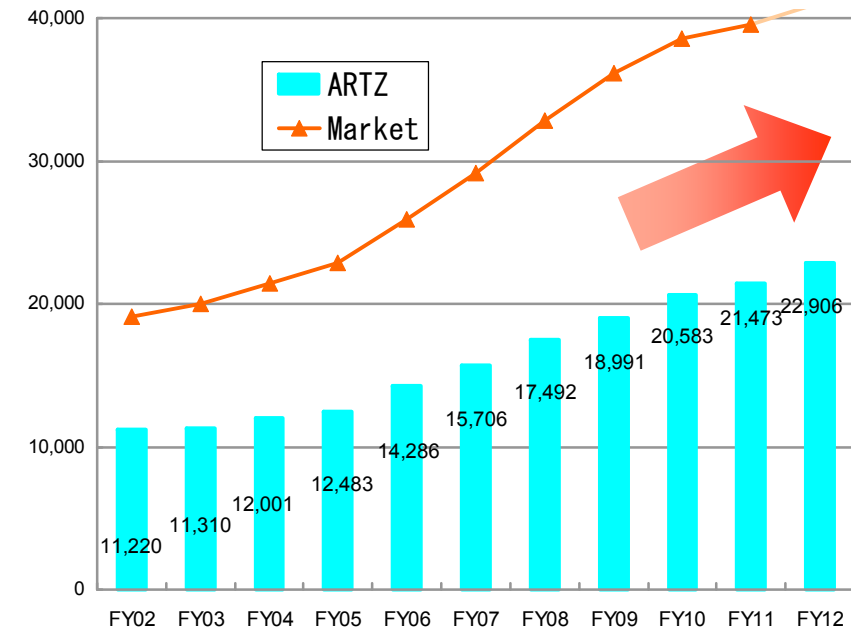
■ Growing Elderly Population (65 or over)

(Source: Ministry of Internal Affairs and Communications)

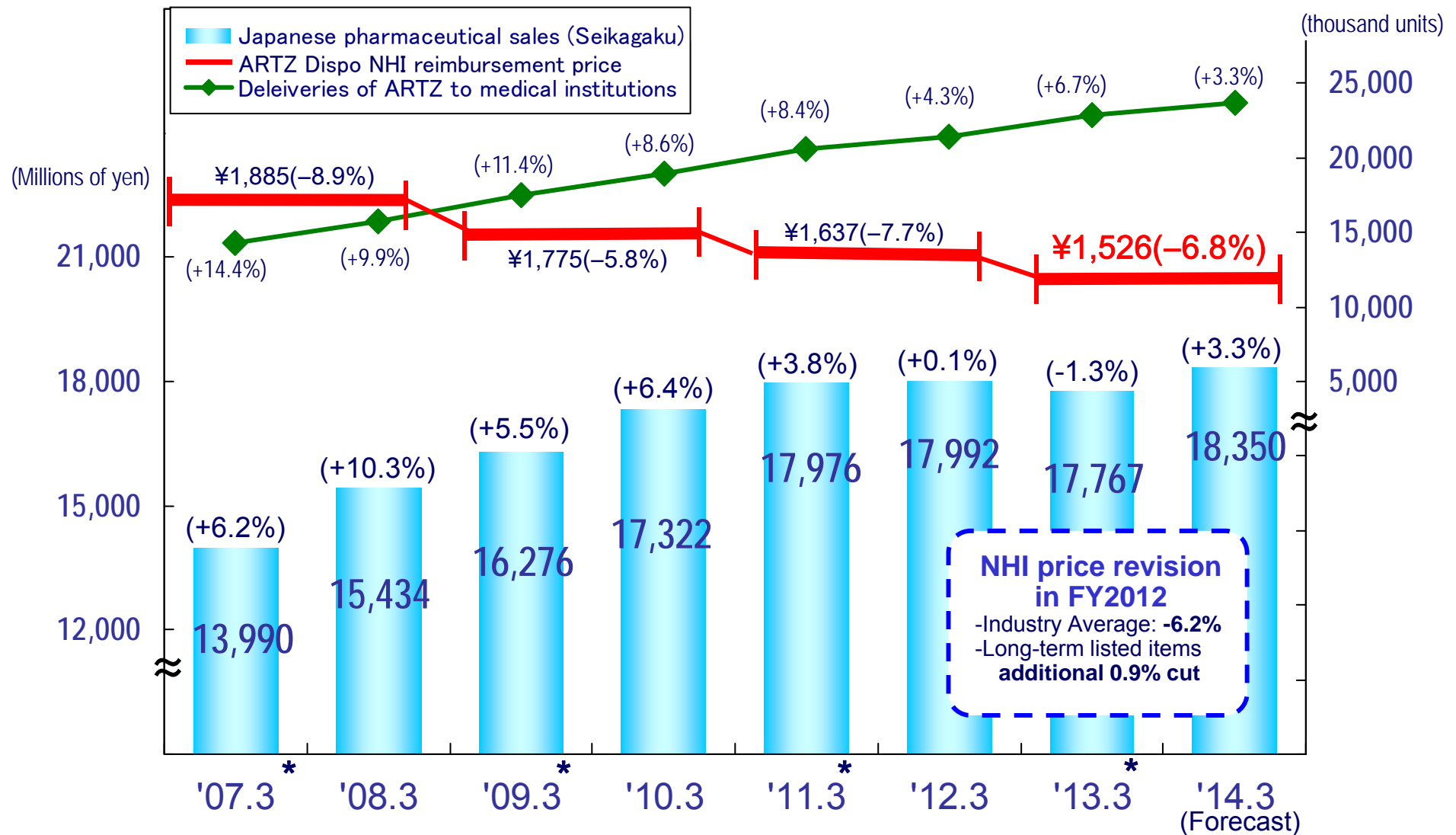


■ Deliveries of ARTZ® to Medical Institutions (Japan)

(Thousand units)



Trend in NHI Reimbursement Price and Our Domestic Pharmaceuticals Sales



* National Health Insurance drug price revision

Market Expansion through Disease Awareness Campaigns

Ads placed in publications including the Asahi Shimbun national morning edition (September: 3 times)

Articles posted on a comprehensive lifestyle information website

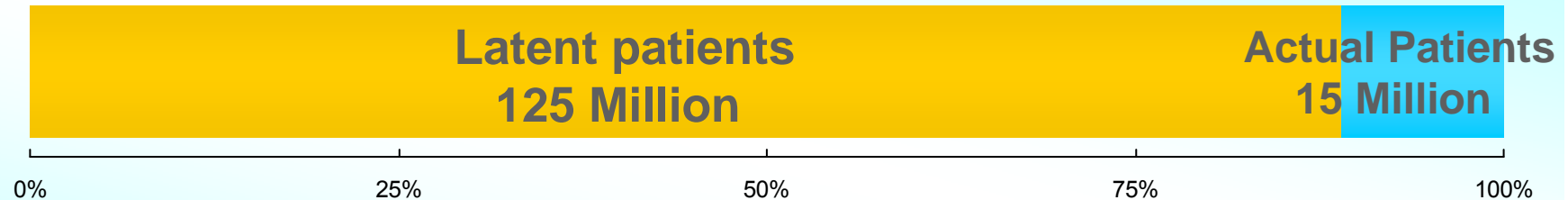


Morning Edition of Asahi Shimbun (September 18, 2013)

Two articles from a series of total six articles on knee osteoarthritis posted

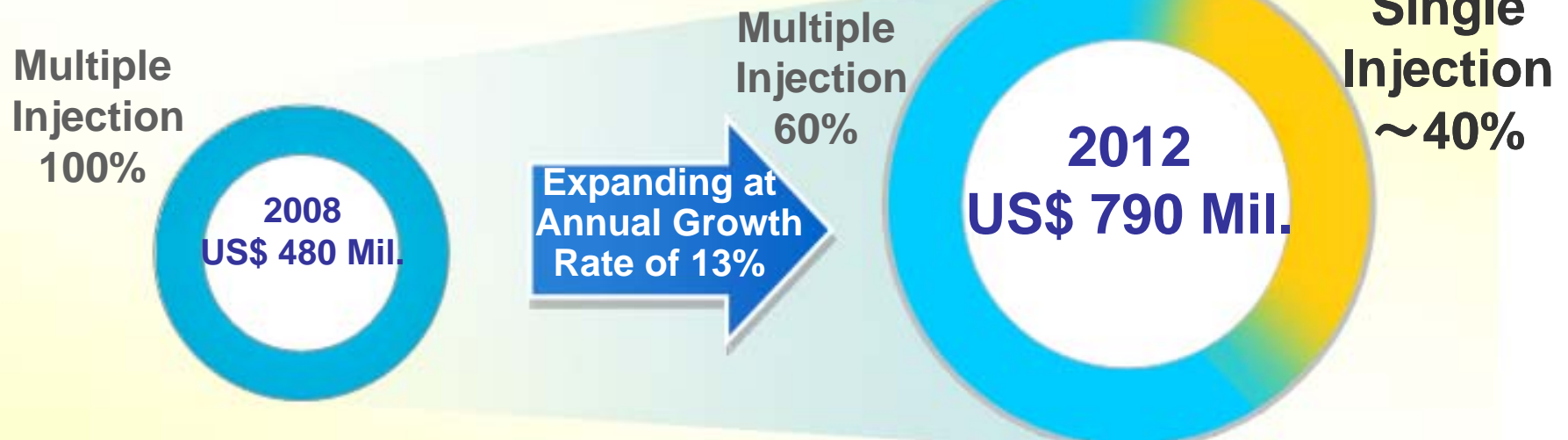
U.S. Market for Hyaluronic Acid Products

■ Number of osteoarthritis patients (estimate)



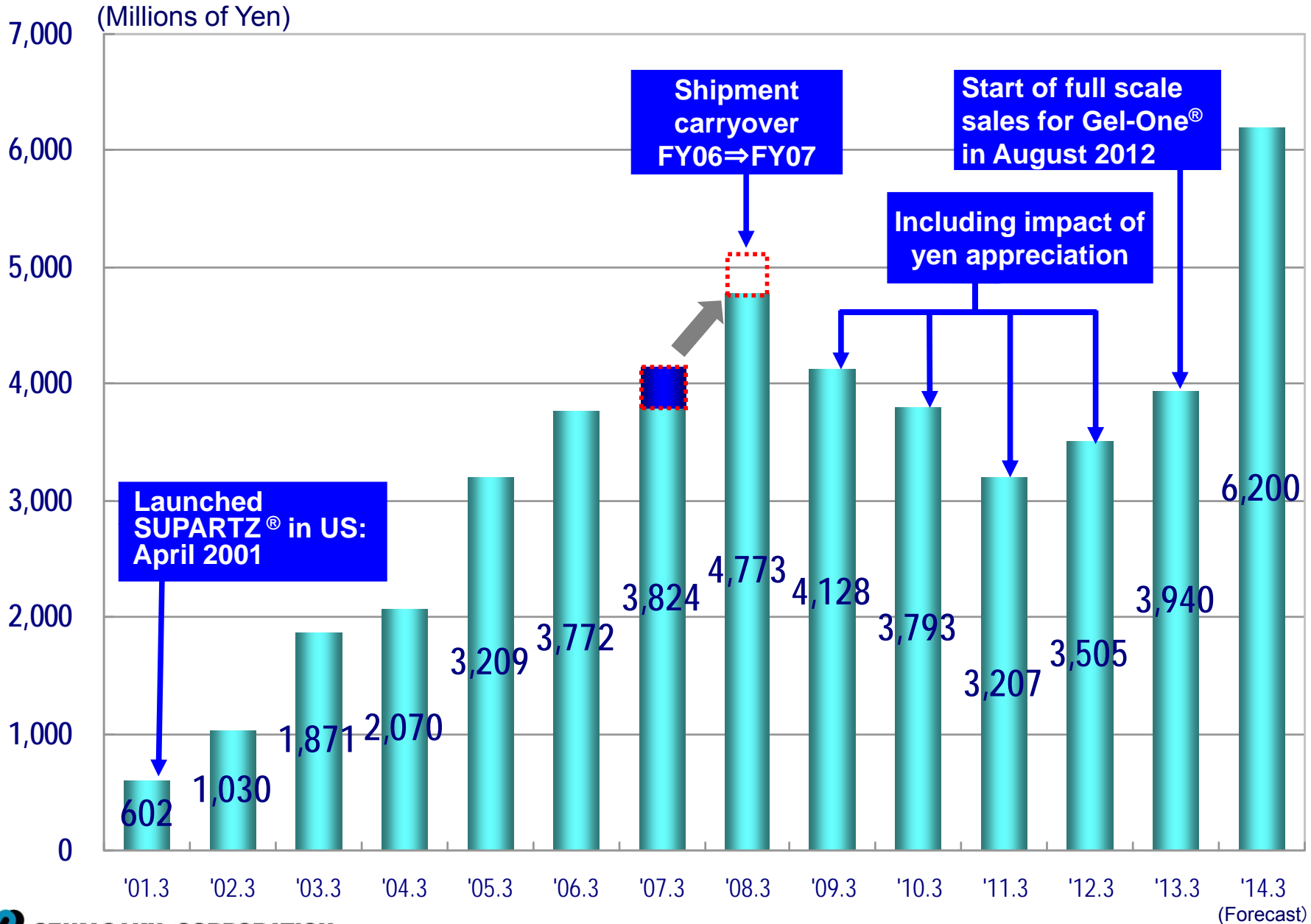
- ◆ Ratio of patients using hyaluronic acid products is less than 10% of patients receiving any treatment for osteoarthritis.
⇒ There is a large room to expand.

■ Trend in market size (estimate)



- ◆ The market has been expanding since the launch of a single injection product in 2009

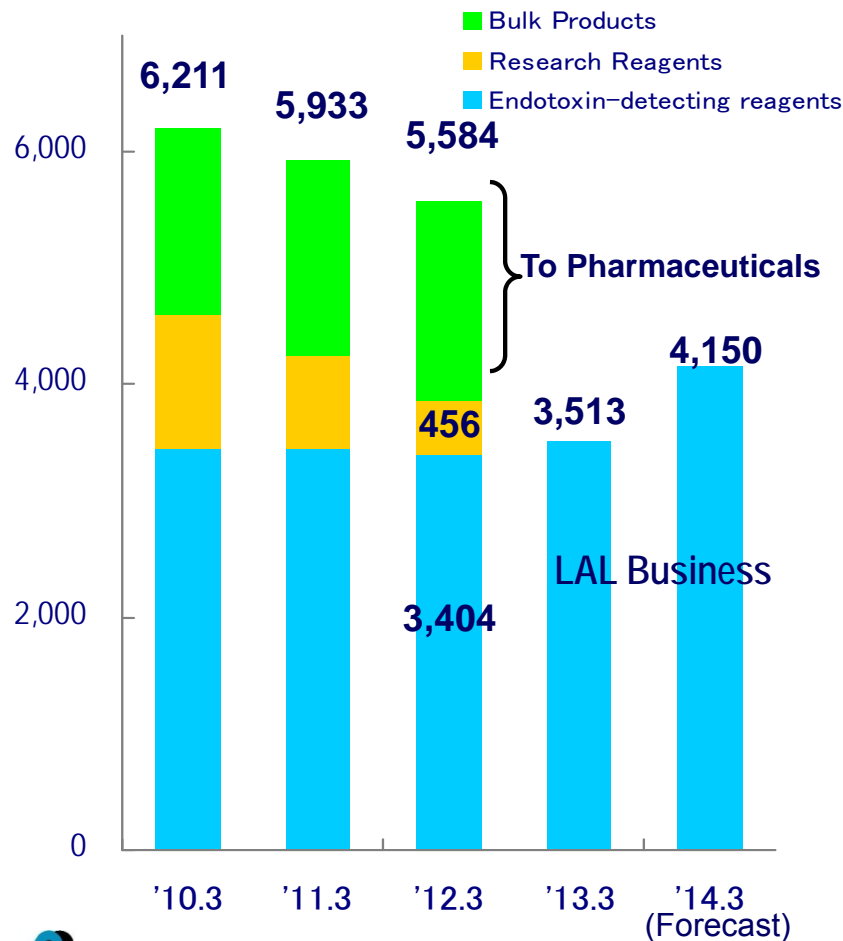
Trend in Hyaluronic Acid Products in Overseas Market



Sales of LAL Business (Value Basis/ year-on-year)

Sales of LAL Business

(Millions of Yen)



FY2013 1H Results +17.0%

Japan: Slight decrease from discontinuation of sales of in-vitro diagnostic agents

Overseas: Increase due to higher sales of endotoxin-detecting reagents and the impact of yen depreciation

FY2013 Forecast: +18.1%

Japan: Sales mostly unchanged on increases for research reagents and equipment, despite discontinuation of in-vitro diagnostic agents

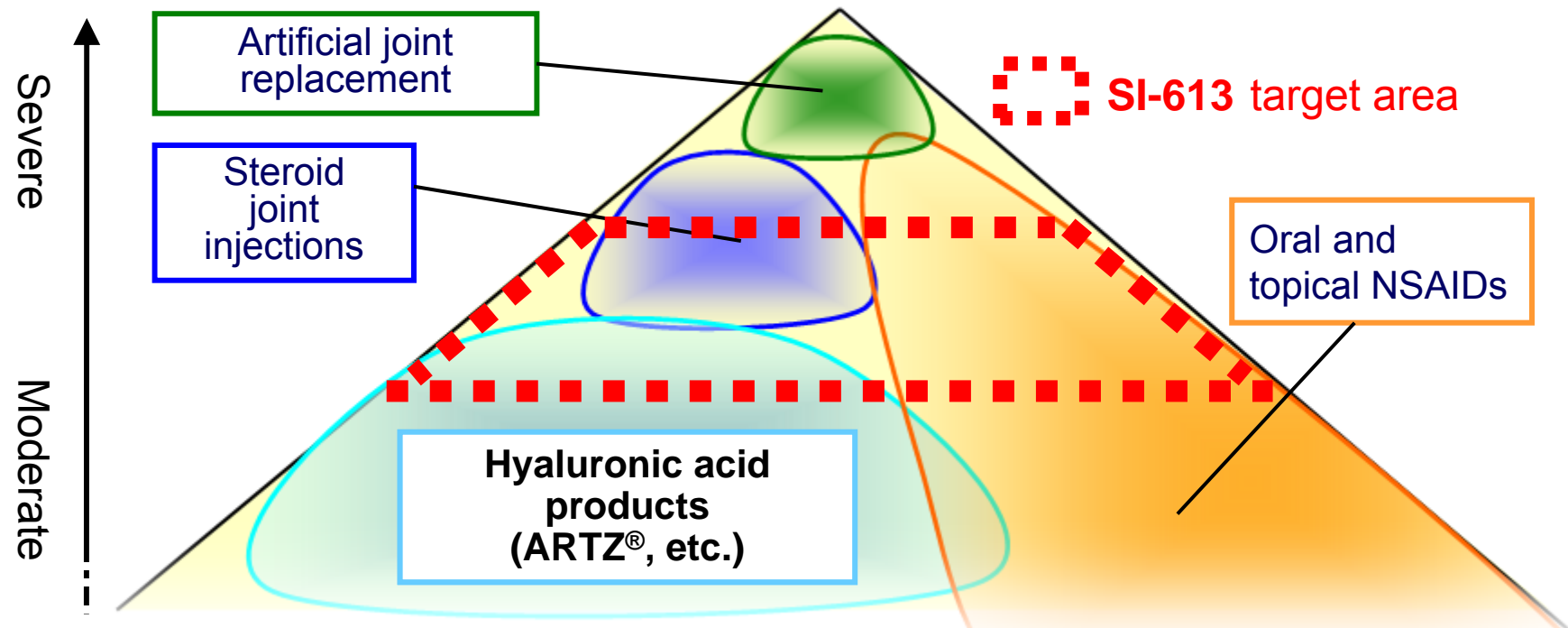
Overseas: Increase partly attributable to the impact of yen depreciation on sales of endotoxin-detecting reagents

Segment Changes

Business segments have been changed beginning in FY2012 due to the discontinuation of the research reagents business and the absorption-type merger of Seikagaku Biobusiness. Bulk Products will be included in the pharmaceuticals segment, and endotoxin-detecting reagents will be reported as the LAL segment.

SI-613 Target Patients

■ Patients with severe pain and being treated with oral or topical NSAIDs or intra-articular steroid injection



■ **Target market size in Japan**
(Including applications outside the knee)

Oral NSAIDs:	~¥100 billion
Topical NSAIDs:	~¥200 billion
HA injections:	~ ¥55 billion
Steroid injections:	~ ¥15 billion

SI-615 Outline

- Oral agent for rheumatoid arthritis in-licensed from CanFite
- Reassessing future development policy based on progress with PIIb trial by the licensor

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

Japan: PI

Phase I single administration clinical trial completed in May 2009

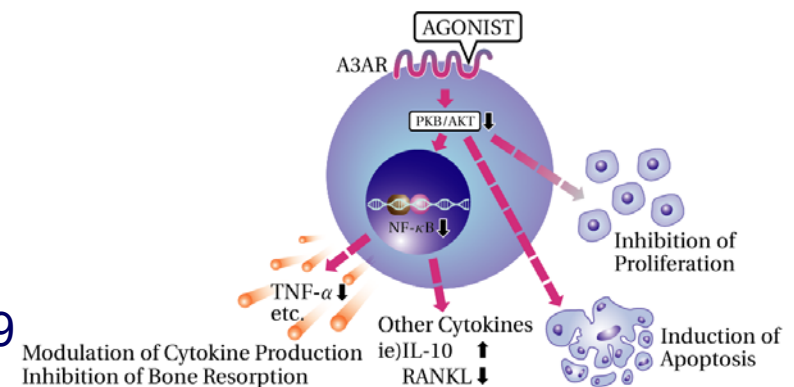
Europe: PIIb

Implemented by Can-Fite

⇒ Seikagaku will reassess its future development policy based on 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.



Special Profile

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

1st *Specialization in glycoscience*

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

2nd *Unique business model*

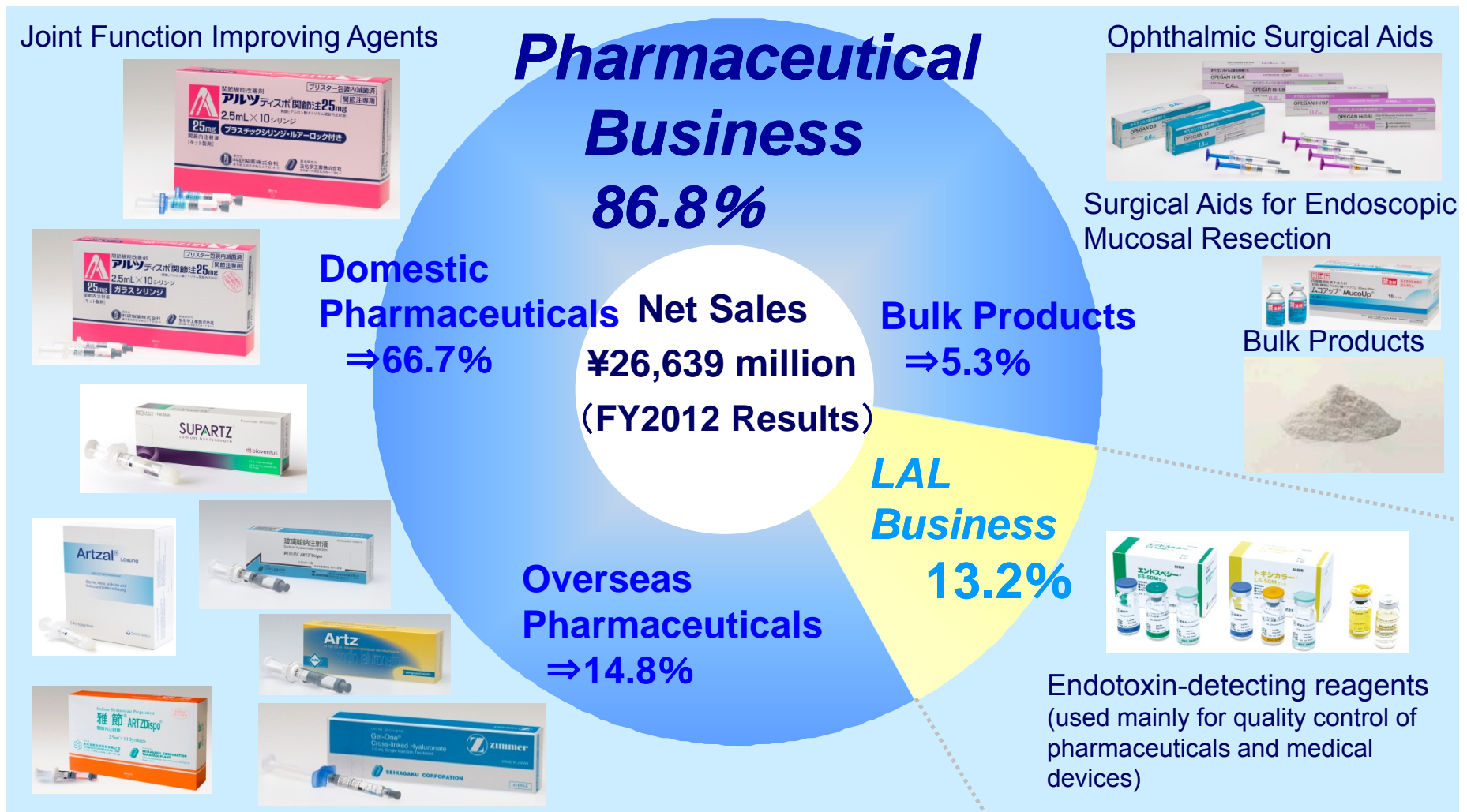
- Concentration on R&D and manufacturing
- R&D staff comprising **one-third** of our total employees
- Allocation of over **20%** of net sales to R&D investment

3rd *High-level extraction & purification technologies*

- ARTZ[®] (main product) has been administered in more than **300 million** injections without major side effects over more than **25 years**

Our Business Segment

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



Main Hyaluronic Acid (HA) Products

■ Main products produced from hyaluronic acid

■ **ARTZ[®]** Knee osteoarthritis (OA) pain relief by multiple injections

- ◆ *The first* HA joint function improving agent *in the world*
- ◆ *The world's No.1* injectable HA product, approved in *18 countries*
- ◆ Main distributors:
 - Kaken Pharmaceutical (Japan)
 - Bioventus (U.S.)
 - Kunming Baker Norton Pharmaceutical (China)



■ **Gel-One[®]** Knee osteoarthritis pain relief by a single injection

- ◆ A joint function improving agent having *cross-linking hyaluronate hydrogel* with *high viscosity* as a main ingredient
- ◆ Launched in the U.S. in January 2012
- ◆ Distributor: Zimmer (U.S.)



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.