

Exploring the Innovative Promise of Glycoscience

Financial Results for the First Half of Fiscal Year 2017

(April 1, 2017 – September 30, 2017)



<http://healthy-knee.com/>



SEIKAGAKU CORPORATION

(TSE:4548)

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Overview for 1H of FY2017

(Millions of Yen)	1H FY2017 Results	Year-on-Year		(Reference) FY2017 Full Year Forecasts	
		Change	% of Change	FY 2017 Forecasts	Degree of Progress
Net sales	15,495	+410	+2.7%	30,300	51.1%
Operating Income	2,218	+1,435	+183.4%	1,500	147.9%
Ordinary Income	4,794	+3,418	+248.3%	3,750	127.9%
Net Income	3,550	+2,537	+250.4%	2,700	131.5%
R&D Expenses (Ratio to net sales)	3,205 (20.7%)	-903 (-6.5pt)	-22.0%	8,350 (27.6%)	38.4%
Average Exchange Rate (1US\$)	¥111.07	+¥5.72		¥108.00	

	1H FY2017 Results	1H FY2016 Results	(Reference) FY2017 Forecasts
Net Income per Share	¥62.73	¥17.87	¥47.65

Net sales by Business Segment (1H of FY2017)

(Millions of Yen)	1H FY2017 Results	Year-on-Year	% of Change
Net sales	15,495	+410	+2.7%
Pharmaceuticals	12,559	+277	+2.3%
Domestic Pharmaceuticals	8,453	-65	-0.8%
Overseas Pharmaceuticals	3,586	+359	+11.1%
Bulk Products	519	-16	-3.1%
LAL Business	2,936	+133	+4.7%
(Overseas sales)	6,020	+612	+11.3%

*Foreign exchange impact on overall net sales:
approx. +190 million yen

Domestic Pharmaceuticals

➤ ARTZ (Joint function improving agent)

- Seikagaku sales down slightly reflecting a backlash from a sales increase in the same period of fiscal 2016 accompanying the introduction of new syringes



ARTZ:
Joint function improving agent with hyaluronic acid as its main ingredient

➤ OPEGAN series (Ophthalmic surgery aid)

- Seikagaku sales up due to steady progress for market penetration of SHELLGAN



SHELLGAN:
New OPEGAN series product used in cataract surgery (launched July 2016)

➤ MucoUp (Submucosal injection agent for endoscopic surgery)

- Seikagaku sales at the prior-year level

Net sales by Business Segment (1H of FY2017)

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*Foreign exchange impact on overall net sales:
approx. +190 million yen

Overseas Pharmaceuticals

➤ Gel-One in the U.S. (Single injection)

- Local sales up approx. 20% on a volume basis
- Seikagaku sales at the prior-year level due to concentration of shipments in 1H FY2016 and the impact of a decline in local selling prices

➤ ARTZ (Multiple injection)

- SUPARTZ FX in the U.S:
 - Local sales down slightly amid fierce competition
 - Seikagaku sales up as a result of concentration of shipments accompanying a sales partner inventory buildup
- ARTZ in China:
 - Local sales up slightly, with the government's price-curbing policy running its course
 - Seikagaku sales down due to local inventory adjustments

Net sales by Business Segment (1H of FY2017)

(Millions of Yen)	1H FY2017 Results	Year-on-Year	% of Change
Net sales	15,495	+410	+2.7%
Pharmaceuticals	12,559	+277	+2.3%
Domestic Pharmaceuticals	8,453	-65	-0.8%
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(Overseas sales)	6,020	+612	+11.3%

*Foreign exchange impact on overall net sales:
approx. +190 million yen

Bulk Products

- Sales of hyaluronic acid at the prior-year level, but overall sales down slightly due to timing of chondroitin sulfate shipments

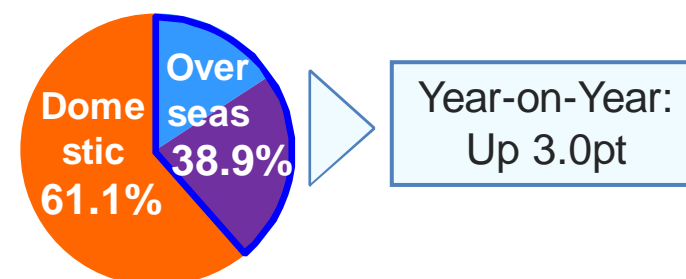
*Bulk Products:
High-purity, high-quality hyaluronic acid and chondroitin sulfate for pharmaceuticals

LAL Business

- Increase in overseas sales, despite a decrease in sales to dialysis facilities in Japan

*LAL Business:
The manufacturing and sales of Endotoxin detection reagents used in the quality control of pharmaceuticals

Overseas Sales Ratio



■ Overseas LAL/Bulk ■ Overseas Pharmaceuticals ■ Domestic sales

Income for 1H of FY2017 (Year-on-Year)

(Millions of Yen)	1H FY2017 Results	Year-on-Year	% of Change
Net sales	15,495	+410	+2.7%
Cost of Sales (Cost of Sales ratio)	6,517 (42.1%)	-53 (-1.5pt)	-0.8%
SGA expenses	6,759	-971	-12.6%
R&D Expenses (to Net sales ratio)	3,205 (20.7%)	-903 (-6.5pt)	-22.0%
Operating Income (to Net sales ratio)	2,218 (14.3%)	+1,435 (+9.1pt)	+183.4%
Ordinary Income	4,794	+3,418	+248.3%
Net Income	3,550	+2,537	+250.4%
Depreciation	1,468	+16	+1.1%

Operating Income

Cost of Sales ratio (-1.5pt):

Decrease due to improvement in production efficiency in connection with a change of syringe, the impact of yen depreciation, and other factors

SGA Expenses (-971):

- Recording in 1H FY2016 of substantial expenses associated with the open-label trial for SI-6603 in the U.S.
- Slippage of planned R&D expenses to the third quarter or later

Net Income

Non-operating Income / Expenses (+1,982):

- Sharp increase in royalty income (+1,434)
- Gain on valuation of foreign currency-denominated assets accompanying yen depreciation, compared with a loss in 1H FY 2016 (+295)

Income Taxes (Tax Rate: 25.9%):

Decrease due to the impact of the Japan-U.S. profit contribution ratio (-0.5pt)

Overview of Forecasts in FY2017

*No change from the results forecast announced May 12, 2017

(Millions of Yen)	FY2017 Forecasts	FY2016 Results			(Reference) Degree of 1H Progress
		Results	Change	% of Change	
Net sales	30,300	29,589	+710	+2.4%	51.1%
Operating Income	1,500	1,282	+217	+17.0%	147.9%
Ordinary Income	3,750	2,477	+1,272	+51.4%	127.9%
Net Income	2,700	1,787	+912	+51.0%	131.5%
R&D Expenses (to Net sales ratio)	8,350 (27.6%)	7,834 (26.5%)	+515 (+1.1pt)	+6.6%	38.4%
Average Exchange Rate (1US\$)	¥108.00	¥108.42	- ¥0.42		

	FY2017 Forecasts	FY2016 Results	Exchange Rate Sensitivity (Impact of a change of ¥1 against the US\$)	
Net Income per share	¥47.65	¥31.55	Net sales	Approx. ¥110 million
Dividend per share	¥26.00	¥31.00*	Operating income	Approx. ¥45 million
Dividend Payout ratio	54.6%	98.3%		

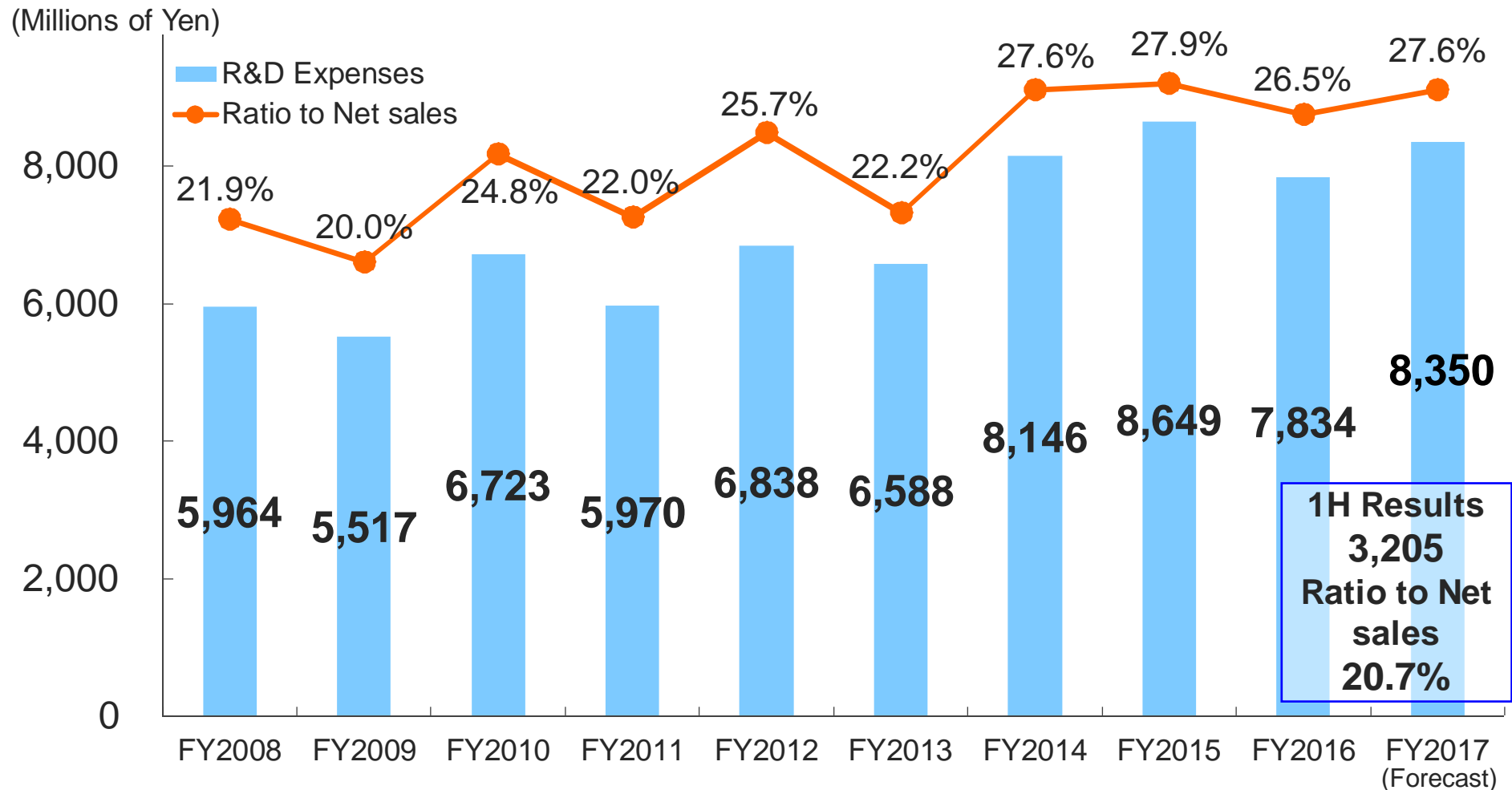
* including a 70th anniversary commemorative dividend of ¥5 per share

Trend in R&D Expenses

*No change from the results forecast announced May 12, 2017



Although R&D expenses remain at a high level

(25-30% of net sales), engaging in efficient, prioritized R&D



Domestic Pharmaceuticals

(unit deliveries to medical institutions/Year-on-Year)

Joint-function improving agent ARTZ	1H FY2017 Results	FY2017 Forecasts	
	<ul style="list-style-type: none"> ● Impact of an increase in deliveries accompanying the introduction of new syringes in 1H FY2016 ● Increase in sales of some generics 	<ul style="list-style-type: none"> ● Promote in ARTZ 30th anniversary commemorative activities ● Aim for growth exceeding the market growth rate 	
	<p>ARTZ growth rate: -1.4% (Market growth rate: -0.2%) Market share: 58.3% (-0.7pt)</p>	<p>● ARTZ growth rate +1.0% (forecast)</p>	<p>● Market share 58.9% (forecast)</p>
Ophthalmic surgical aids OPEGAN (including SHELLGAN)	1H FY2017 Results	FY2017 Forecasts	
	<ul style="list-style-type: none"> ● Market penetration of SHELLGAN proceeding faster than expected ● Substantial recovery in market share 	<ul style="list-style-type: none"> ● Retake share from competitors ● Publicize SHELLGAN product features not available from competitors 	
	<p>OPEGAN growth rate: +25.0% (Market growth rate: +1.8%) Market share: 41.7% (+7.7pt)</p>	<p>● OPEGAN growth rate +17.6% (forecast)</p>	<p>● Market share 42.0% (forecast)</p>

Overseas Pharmaceuticals

(1H FY2017 Results Year-on-Year / value basis)

Overseas Pharmaceuticals 1H Sales trend

FY2017 1H Results
+11.1%

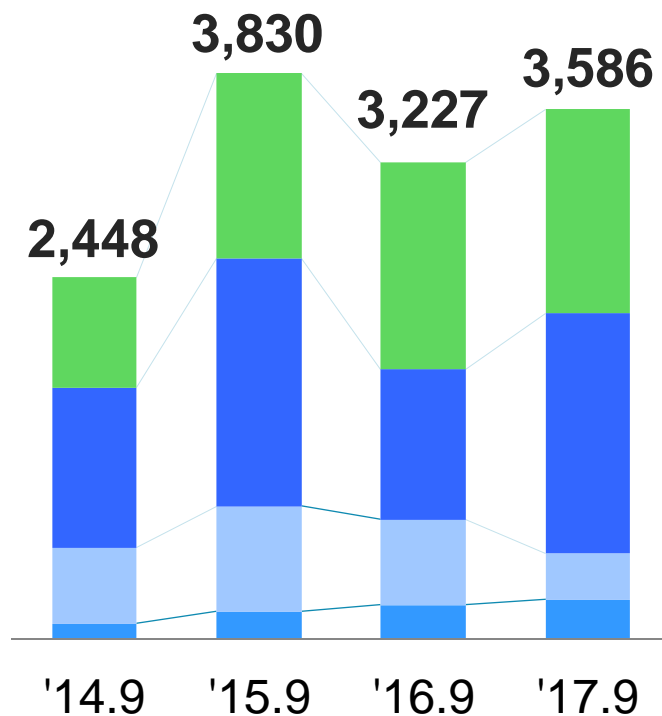
Increase due to concentration of shipments of multiple injection products in the U.S. and the impact of yen depreciation

*Foreign exchange impact: approx. +¥180 million

(Millions of Yen)

<Breakdown>

■ Gel-One ■ SUPARTZ FX in the U.S.
■ ARTZ in China ■ Others



Gel-One (single injection)

- **Sales in the U.S.:** Growth of approx. 20% (volume basis)
- **Seikagaku exports:** Sales at the prior-year level due to the impact of concentration of shipments in 1H FY2016 and a decline in local selling prices accompanying price adjustments for some major customers to increase share

ARTZ (multiple injection)

- **SUPARTZ FX in the U.S.**
Local sales down slightly despite fierce competition
- **ARTZ in China**
With the government's price-curbing policy running its course, a return to growth in local sales
(volume basis: 3% year-on-year increase)
- **Seikagaku exports**
Local inventory adjustments in China, but shipments of SUPARTZ FX to the U.S. up due to a distributor inventory buildup

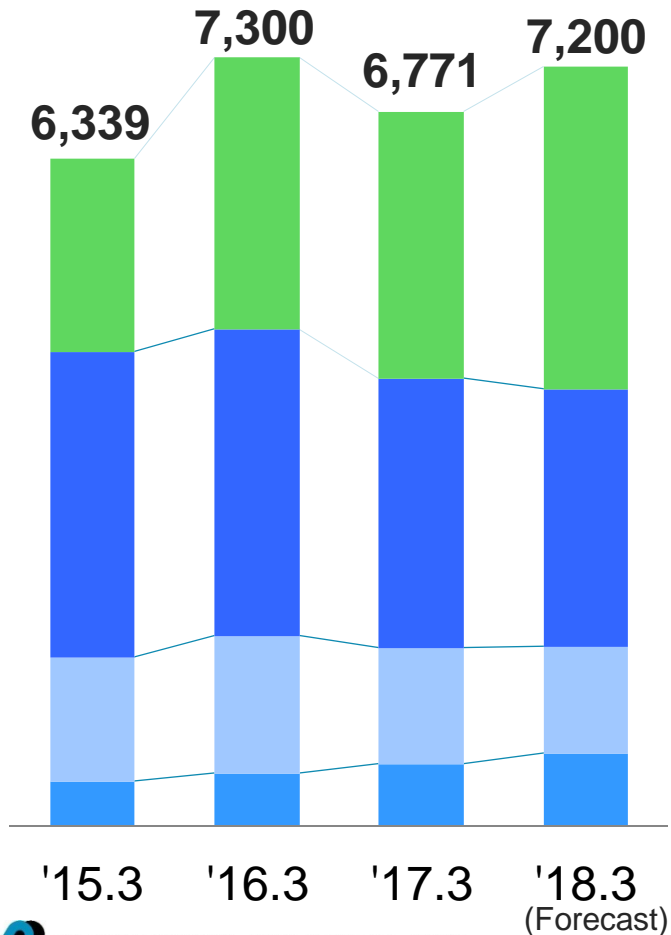
Overseas Pharmaceuticals (FY2017 Forecast Year-on-Year / value basis)

Overseas Pharmaceuticals Sales trend

(Millions of Yen)

<Breakdown>

■ Gel-One ■ SUPARTZ FX in the U.S.
■ ARTZ in China ■ Others



*No change from the results forecast announced May 12, 2017

FY2017 Forecast
+6.3%

Sales increase from an expected increase in Gel-One in the U.S.

*Foreign exchange impact: approx. -¥40 million

Gel-One (single injection)

- **Sales in the U.S.:** Forecast of 20% growth (volume basis) in light of the local sales situation
- **Seikagaku exports:** Exports weaker than the initial forecast
Sales promotion measures to be implemented together with the sales partner

ARTZ (multiple injection)

- **SUPARTZ FX in the U.S.**
Sales decrease expected to be smaller than in the initial forecast
- **ARTZ in China**
Aiming for a local sales increase through strengthening of sales promotion, such as sales force expansion
- **Seikagaku exports**
Inventory adjustments in China expected to continue
Stronger than expected sales of SUPARTZ FX in the U.S.

Sales of LAL Business (value basis/year-on-year)

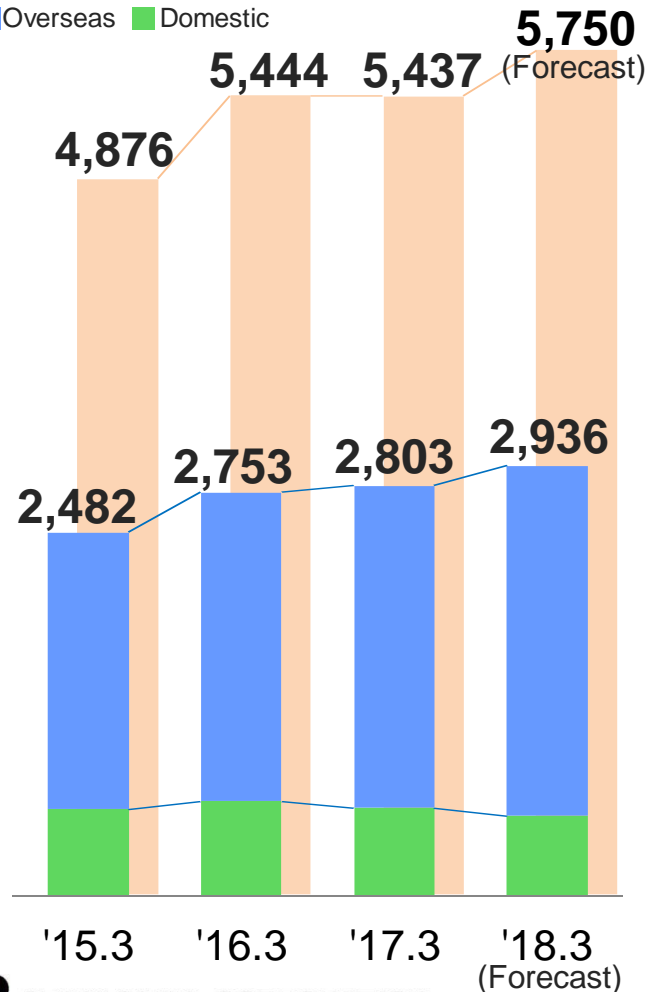
LAL Business Sales trend

(Millions of Yen)

Full year

<1H Breakdown>

Overseas Domestic



1H FY2017 Results: +4.7% (Year-on-Year)

Overseas

Increase in sales of endotoxin detection reagents used in quality control and other products

Domestic

Decrease in sales to dialysis facilities in connection with a change in water quality control standards

FY2017 Forecast: +5.8% (Year-on-Year)

*No change from the results forecast announced May 12, 2017

Overseas

Strengthening of sales activities in Europe by U.S. subsidiary Associates of Cape Cod (ACC)

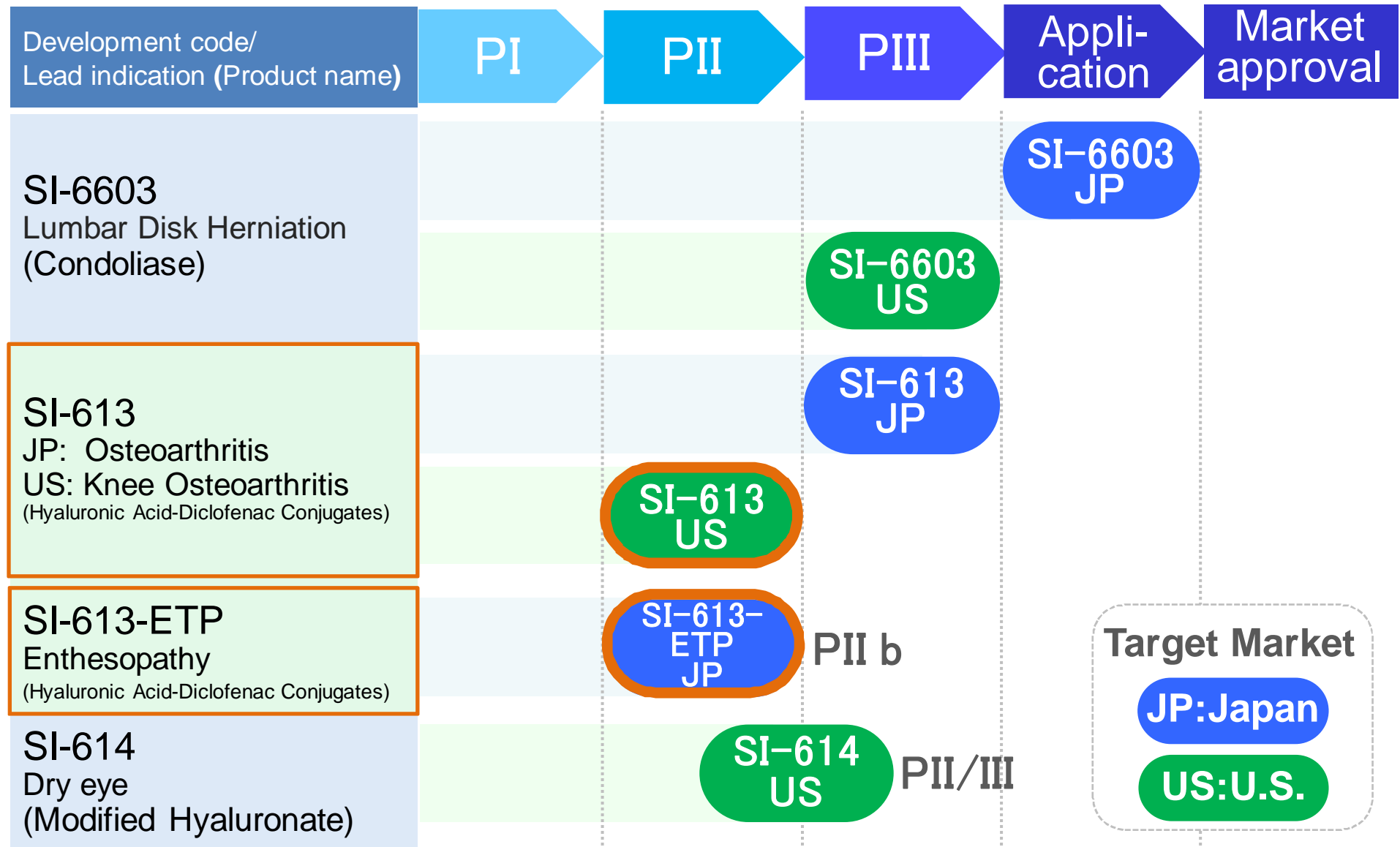
Domestic

Decrease in sales to dialysis facilities

LAL Business: The manufacturing and sales of Endotoxin detection reagents* used in the quality control of pharmaceuticals

*Endotoxin detection reagents are reagents whose main ingredient is Limulus Amebocyte Lysate (LAL).

Pipeline List (Research and Development themes)



SI-6603 Outline (Treatment for Lumbar Disc Herniation)

Aiming at relieving pain by reducing nerve pressure,
result of shrinking hernias

Japan : NDA filed

- January 2014: NDA filed, examination ongoing
- ⇒ Although it is taking time, the Company believes that the NDA examination is progressing and will continue endeavor to obtain market approval at an early date.

U.S. : PIII

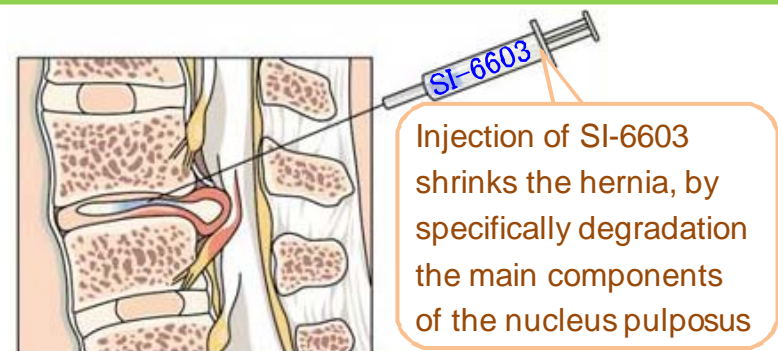
- November 2017 : Disclosed results of the double-blind study and the open-label study
- ⇒ Although the pharmacologic effect and the safety of SI-6603 were confirmed, statistically significant improvement in alleviation of leg pain at 13 weeks, the primary endpoint, was not demonstrated. Seikagaku proceeds with a review and preparations for initiation of a new double-blind study at an early date.

For details; See P20-21

■ SI-6603 Outline

(Treatment for Lumbar Disc Herniation)

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



SI-613 Outline (Treatment of Osteoarthritis & Enthesopathy)

Aiming at prompt and sustained relief of the severe pain and inflammation associated with osteoarthritis and enthesopathy



- Substance: Hyaluronic Acid-Diclofenac Conjugates
- Formulation: Injection into the joint cavity or near the tendon or ligament enthesis

Japan : PIII (Indication: Osteoarthritis) PII b (Indication: Enthesopathy)

- February 2017: Phase III study initiated (three studies planned)
 - ⇒ Knee confirmatory study, study for four sites, long-term administration study
- September 2017: **Definitive agreement on co-development and marketing collaboration in Japan concluded with Ono Pharmaceutical Co., Ltd.**
- September 2017: Late-stage Phase II clinical trial for enthesopathy initiated

U.S. : PII (Indication: Knee osteoarthritis)

- June 2017: Phase II study initiated

Expected Features:

- Provision of prompt and sustained relief of the severe pain and inflammation associated with osteoarthritis and enthesopathy by combining hyaluronic acid with Diclofenac (Anti-Inflammatory Drug) using a proprietary technology, and designing the formulation for sustained release* of the Diclofenac
- Mitigation of NSAID (Non-Steroidal Anti-Inflammatory Drug) side effects reported in oral or topical administration

* Sustained release: Gradual release of active ingredients to achieve a sustained therapeutic effect

Initiatives to maximize the product value of SI-613

Promote in co-development with Ono Pharmaceutical, the product that can be administered to greater numbers of patients

Osteoarthritis: PIII

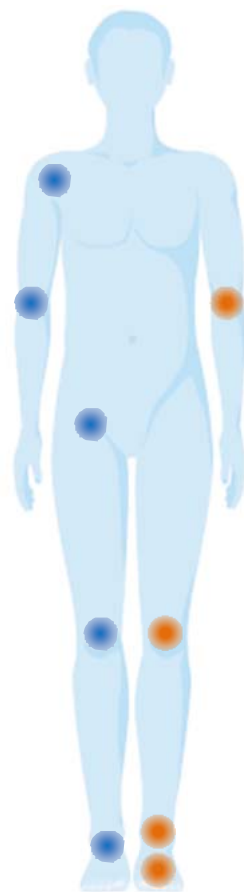
A disease in which joint tissue deteriorates due to abrasion of the articular cartilage, leading to inflammation and pain

Conduct of three clinical trials

- Confirmatory study (knee joint)
- Study for four sites (hip, ankle, elbow, shoulder)
- Long-term administration study (knee joint)

Number of patients examined per year: Approx. 8.7 million

(Seikagaku estimate for five main sites: knee, hip, ankle, elbow, shoulder in Japan)



Enthesopathy: PII b

An inflammatory disease that occurs as a result of excessive load on sites of attachment of ligaments and tendons to other bone or muscle, such as the knee, elbow, heel

Typical examples

- Lateral epicondylitis (tennis elbow)
- Plantar fasciitis
- Patellar tendinitis (jumper's knee)
- Achilles tendonitis, etc.

Number of patients receiving drug therapy per year:

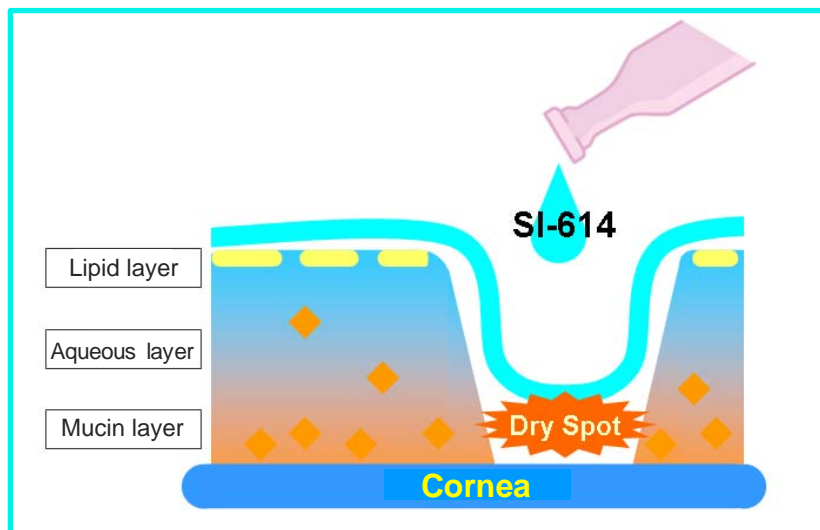
Approx. 0.9 million

(Seikagaku estimate for the above four diseases in Japan)



SI-614 Outline (Treatment of Dry Eye)

Aimed at improvement of symptoms of dry eye by protecting the ocular surface and promoting corneal epithelial wound healing



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

U.S. : PII/III

- January 2015: Phase II/III clinical trials completed
- ⇒ Proceed with consideration of a PIII trial and sales partner search

Expected Features:

- SI-614 is a modified hyaluronate produced by Seikagaku's proprietary technology.
- 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 drugs with relatively strong 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

*No change from the results forecast announced May 12, 2017

Aim to enhance shareholder returns and realize sustained growth by engaging in well-balanced business investment

Shareholder Return Policy

- Aim for stable and continuous dividends from a medium to long term perspective
 - ⇒ Continue to pay **an annual dividend of ¥26 per share**
- Consider purchases of treasury stock, as appropriate, taking into account future business development and the total return ratio

Business Investment

- Business investment in R&D, production system development, and other areas

	FY2012	FY2013	FY2014	FY2015	FY2016	FY2017 (Forecast)
Net Income per share	¥57.33	¥83.55	¥64.27	¥45.39	¥31.55	¥47.65
Annual Total Dividend	¥25.00	¥26.00	¥26.00	¥26.00	¥31.00*	¥26.00
Dividend Payout Ratio	43.6%	31.1%	40.5%	57.3%	98.3%	54.6%

* including a 70th anniversary commemorative dividend of ¥5 per share

Outline of SI-6603 Phase III Clinical Trial in the U.S.

Conducted following 2 clinical trials as phase III in the U.S.

Double Blind Study

(A Multicenter, Randomized, Double-blind, Controlled, Comparative Study)

- **Objective:**
to evaluate efficacy and safety
- **Primary end point:**
improvement of leg pain
at 13 weeks after administration
*VAS; change from baseline
- **Number of patients:** 385
(Planned number: 360)
- **Follow-up period** (after administration):
 - Efficacy: 13 weeks
 - Safety: 104 weeks (2 years)
- **FPI~LPO:**
Oct. 2013 ~ Aug. 2017

Open Label Study

(Un-blind study)

- **Objective:**
to evaluate safety and efficacy
(Primary objective was safety)
- **Primary end point:**
safety of administration
at 26 weeks after administration
- **Number of patients:** 1,011
(Planned number: 1,000)
- **Follow-up period** (after administration):
26 weeks
- **FPI~LPO:**
Apr. 2015 ~ Mar. 2017

*VAS : Visual Analogue Scale

*FPI : First Patient-in, LPO : Last Patient-out

Outline of Result for SI-6603 Phase III Clinical Trial in the U.S.

Significant improvement in the primary endpoint was demonstrated in Phase III study of Japan but it was not made in Phase III study in the U.S.

<Pharmacological effect (Objective indicator)>

- Statistically significant decrease in the intervertebral disc and herniation volume assessed with MRI: **Confirmed pharmacological effect of SI-6603**

<Evaluation of safety>

- No major concern such as adverse reactions was observed: **Confirmed safety of SI-6603**

<Improvement at alleviation of leg pain (Subjective indicator)>

- Statistically significant improvement of leg pain at 13 weeks by VAS was not demonstrated
- ⇒ 1. There is a guideline for diagnostic and pathology of lumbar disc herniation in Japan, however there is no widely used guideline in the U.S. Therefore, there is possibility that some patients out of Japanese guideline were included in the clinical trial in the U.S.
 2. There is possibility that some factors such as complications biased assessment of leg pain

Increasing the certainty of success for the new study by reflecting the knowledge and perception obtained from result of the study

Appendix



Forecasts (Net sales) in FY2017

*No change from the results forecast announced May 12, 2017

(Millions of Yen)	FY2017 Forecasts	Year-on-Year	
		Change	% of Change
Net sales	30,300	+710	+2.4%
Pharmaceuticals	24,550	+397	+1.6%
Domestic Pharmaceuticals	16,350	+81	+0.5%
Overseas Pharmaceuticals	7,200	+428	+6.3%
Bulk Products	1,000	-111	-10.1%
LAL Business	5,750	+312	+5.8%
(Overseas sales)	11,900	+870	+7.9%

Net Sales

Forecast of higher sales with expected sales expansion for Gel-One and the overseas LAL business

Pharmaceuticals Business

Domestic Pharmaceuticals:

- Forecast of sales at the prior-year level for existing products, despite expected growth from SHELLGAN

Overseas Pharmaceuticals:

- Forecast of higher shipments of Gel-One

Bulk Products:

- Sales decrease reflecting fierce competition in the market for hyaluronic acid

LAL Business

Sales expansion at U.S. subsidiary, ACC

*Foreign exchange impact on overall net sales:
approx. - ¥80 million

Forecasts (Income) in FY2017

*No change from the results forecast announced May 12, 2017

(Millions of Yen)	FY2017 Forecasts	Year-on-Year	
		Change	% of Change
Net sales	30,300	+710	+2.4%
Operating Income (to Net sales ratio)	1,500 (5.0%)	+217 (+0.7pt)	+17.0%
Ordinary Income	3,750	+1,272	+51.4%
Net Income	2,700	+912	+51.0%
Cost of Sales ratio	42.1%	-2.7pt	
R&D Expenses (to Net sales ratio)	8,350 (27.6%)	+515 (+1.1pt)	+6.6%
Depreciation	2,950	+29	+1.0%

Income

Increase in income, with the sales increase and improvement in the cost of sales ratio compensating for higher SGA expenses, mainly R&D expenses

Operating Income

Cost of Sales Ratio (42.1%):

- Cost of sales ratio decrease (-2.7pt) in the absence of one-time factor accompanying the introduction of a new syringe for ARTZ

SGA Expenses (approx. +1,000):

- Increase in R&D expenses related to SI-613 and non-clinical themes
- Increase in selling expenses at U.S. subsidiary ACC, and others

Net Income

Non-operating Income (approx. +1,050):

- Planned increase in royalty income

Trend in Capital Investments

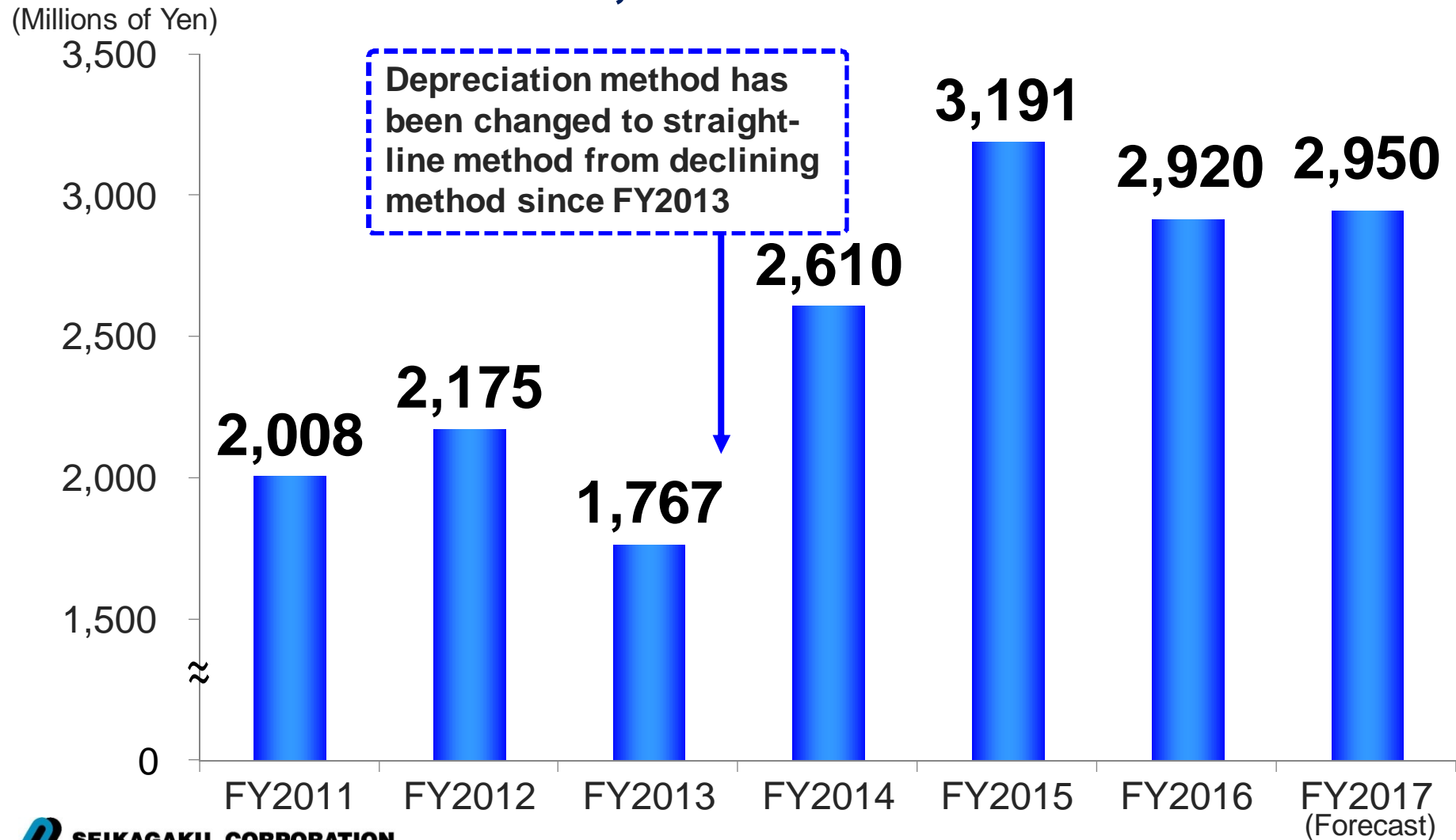
*No change from the results forecast announced May 12, 2017

Facilities	Amounts (¥ bill.)	FY2011	FY2012	FY2013	FY2014	FY2015	FY2016	FY2017 (Forecast)
SI-6603 Bulk Production Facilities	1.1				Start '14.10			
No. 5 Production Building (for ARTZ Dispo)	9.6	Start '12.3				Operation '15.1		
Hyaluronic Acid Bulk Production Facilities	3.1	Start '12.1			Operation '14.2			
Production Facilities for Gel-One	3.0	Start '11.12			Operation '13.10			
Chondroitin Sulfate Bulk Production Facilities	1.2		Operation '12.7					
Amounts (Millions of Yen)		5,718	9,164	7,222	2,095	1,975	1,173	2,000

Trend in Depreciation

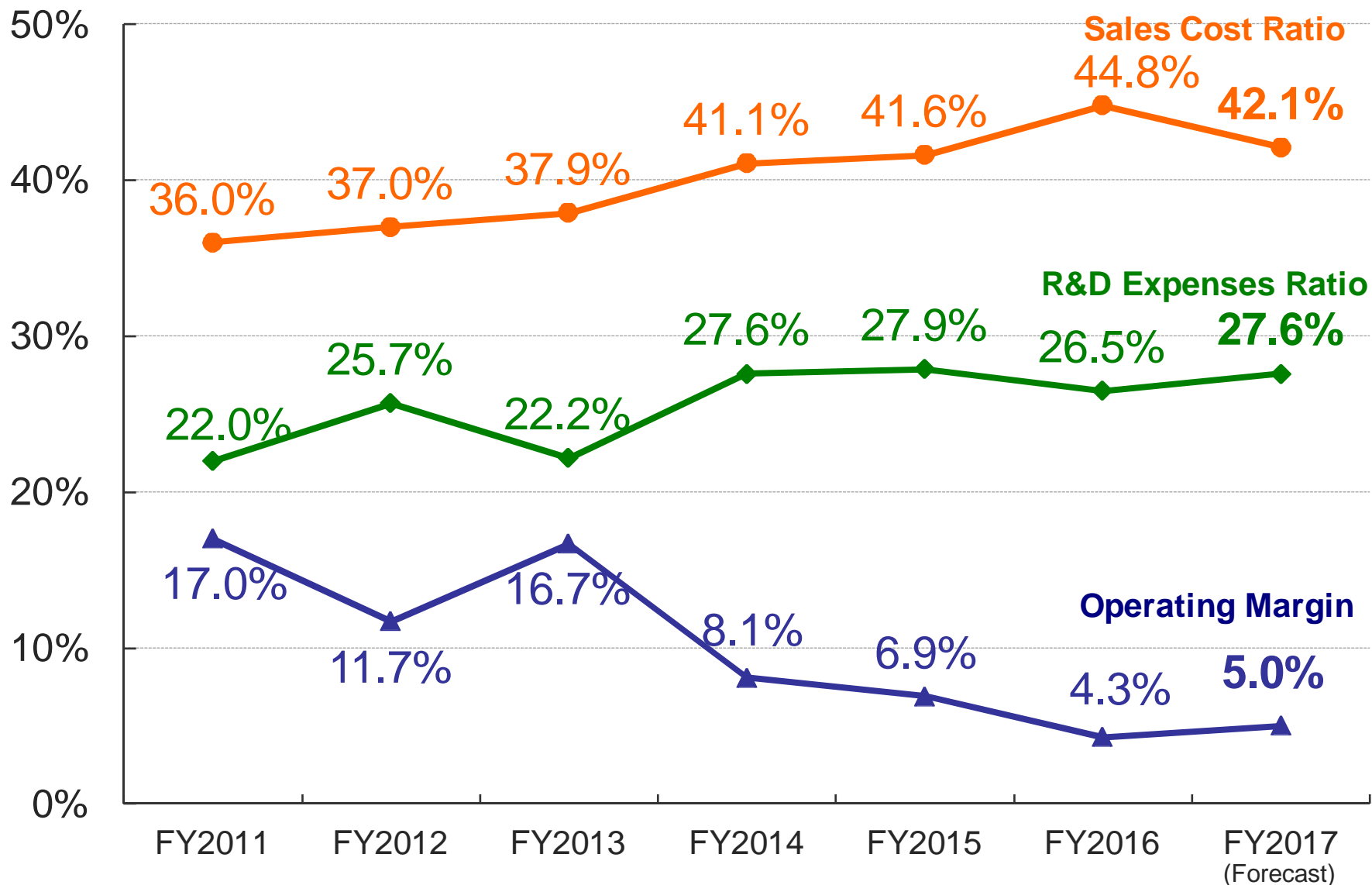
*No change from the results forecast announced May 12, 2017

Depreciation peaked out at FY2015 and anticipate the level of ¥3,000 million from now on



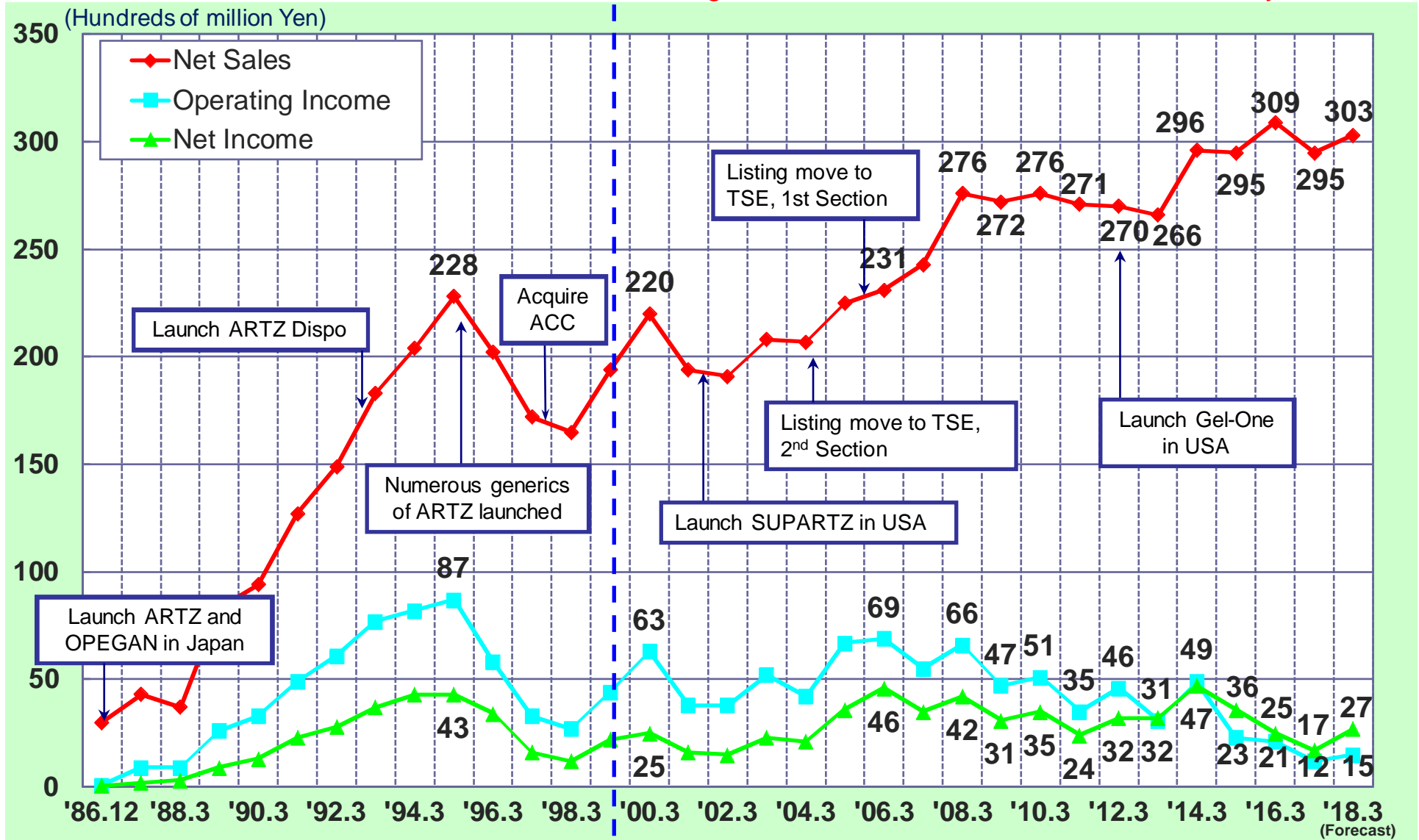
Trend in Financial Index

*No change from the results forecast announced May 12, 2017



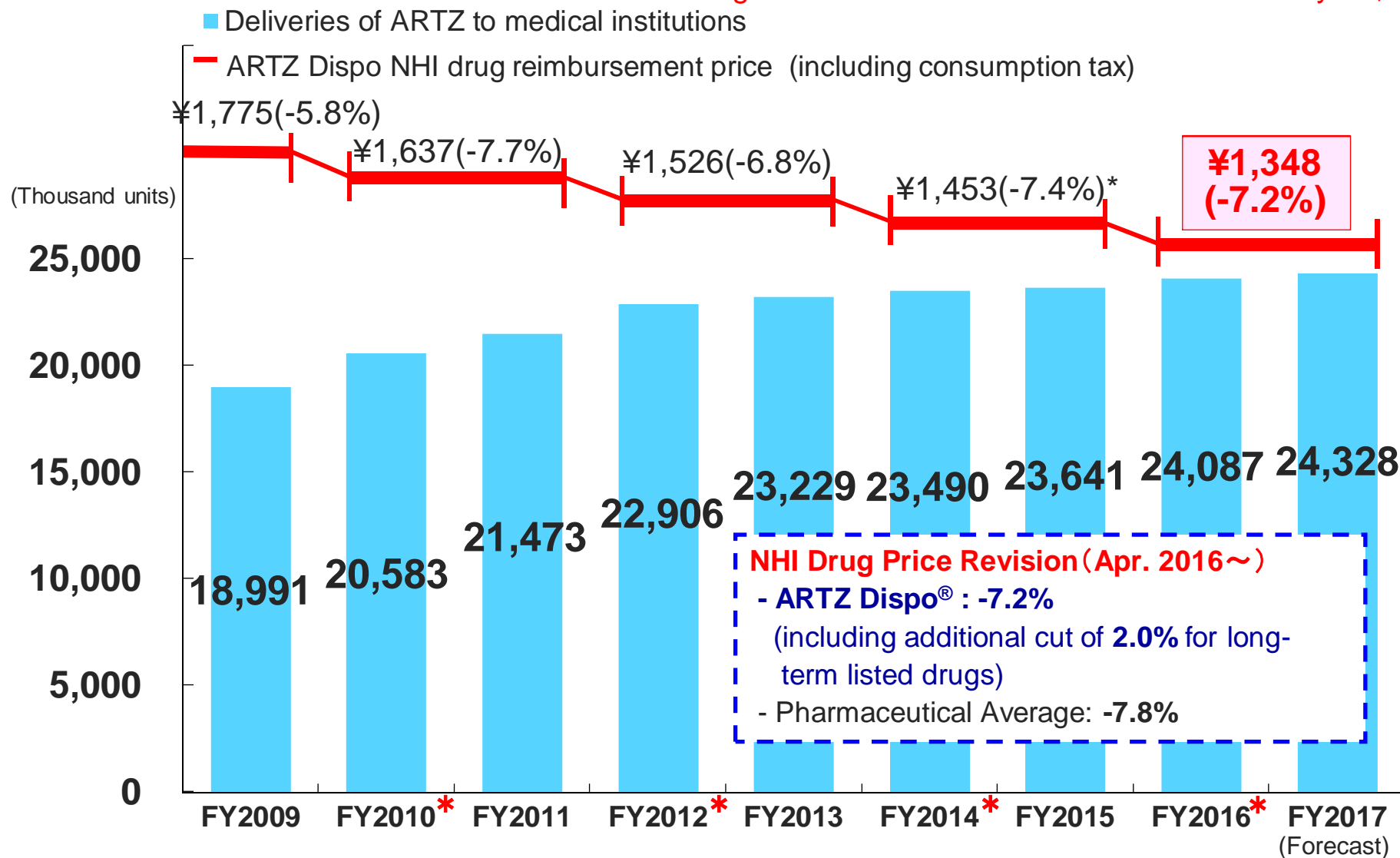
Business Progress & Highlights

*No change from the results forecast announced May 12, 2017



Trend in NHI Reimbursement Price and Trend in Deliveries of ARTZ to Domestic Medical Institutions

*No change from the results forecast announced May 12, 2017



* NHI drug price reduction

* excluding the impact of consumption tax hike

Trend in Deliveries of ARTZ / OPEGAN to Domestic Medical Institutions

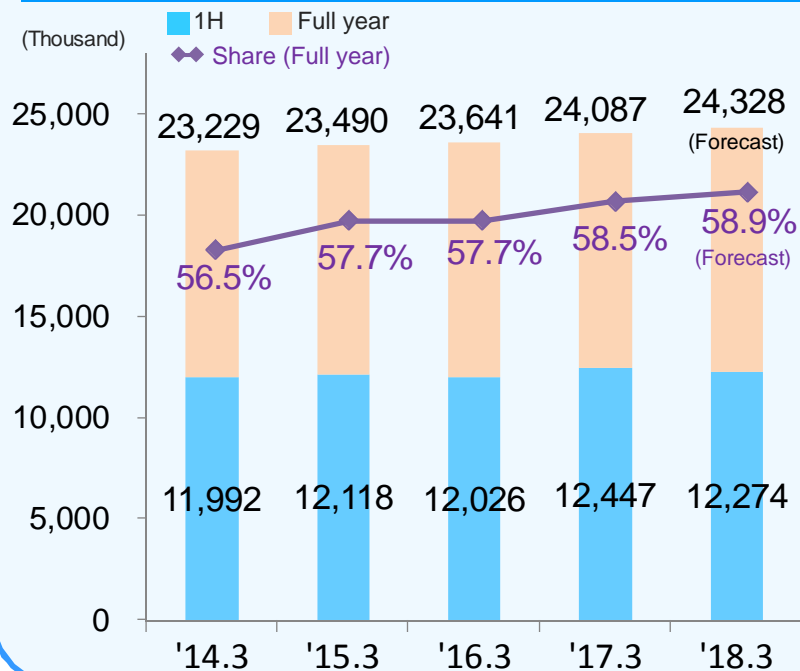
Joint-function improving agent

ARTZ



- The first HA joint function improving agent in the world
- Knee osteoarthritis (OA) pain relief
- Distributor: Kaken Pharmaceutical

Trend in unit deliveries to medical institutions



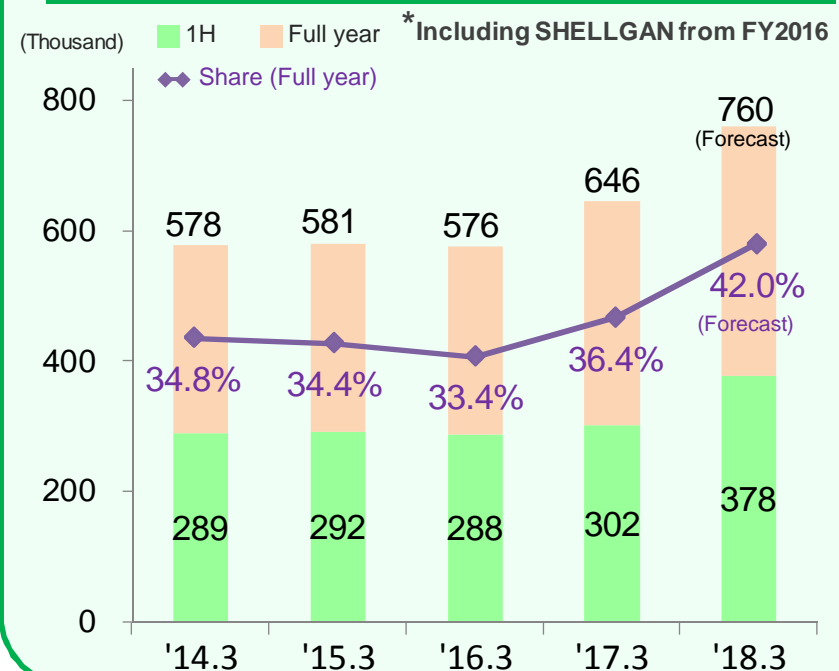
Ophthalmic surgical aids

OPEGAN



- The first domestically HA formulation
- Used in cataract surgery to anterior chamber expansion
- Distributor: Santen Pharmaceutical

Trend in unit deliveries to medical institutions



Ophthalmic Surgical Aid SHELLGAN (Launched July 2016)

眼科手術補助剤 シェルガン® 0.5眼粘弾剤

薬価基準収載

精製ヒアルロン酸ナトリウム/コンドロイチン硫酸エステルナトリウム

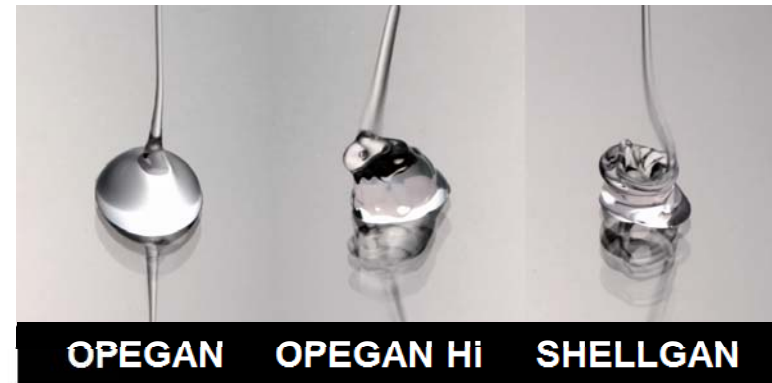


Launch of the new product SHELLGAN

- Suited to a surgical procedure that has become more pervasive in recent years
- Can be stored at room temperature
 - ⇒ A product feature unavailable from competitors
- Strengthening of the OPEGAN series product line
 - ⇒ Seven-product line up provides a wider range of options appropriate to symptoms and physician needs



The OPEGAN series, used mainly in cataract surgery

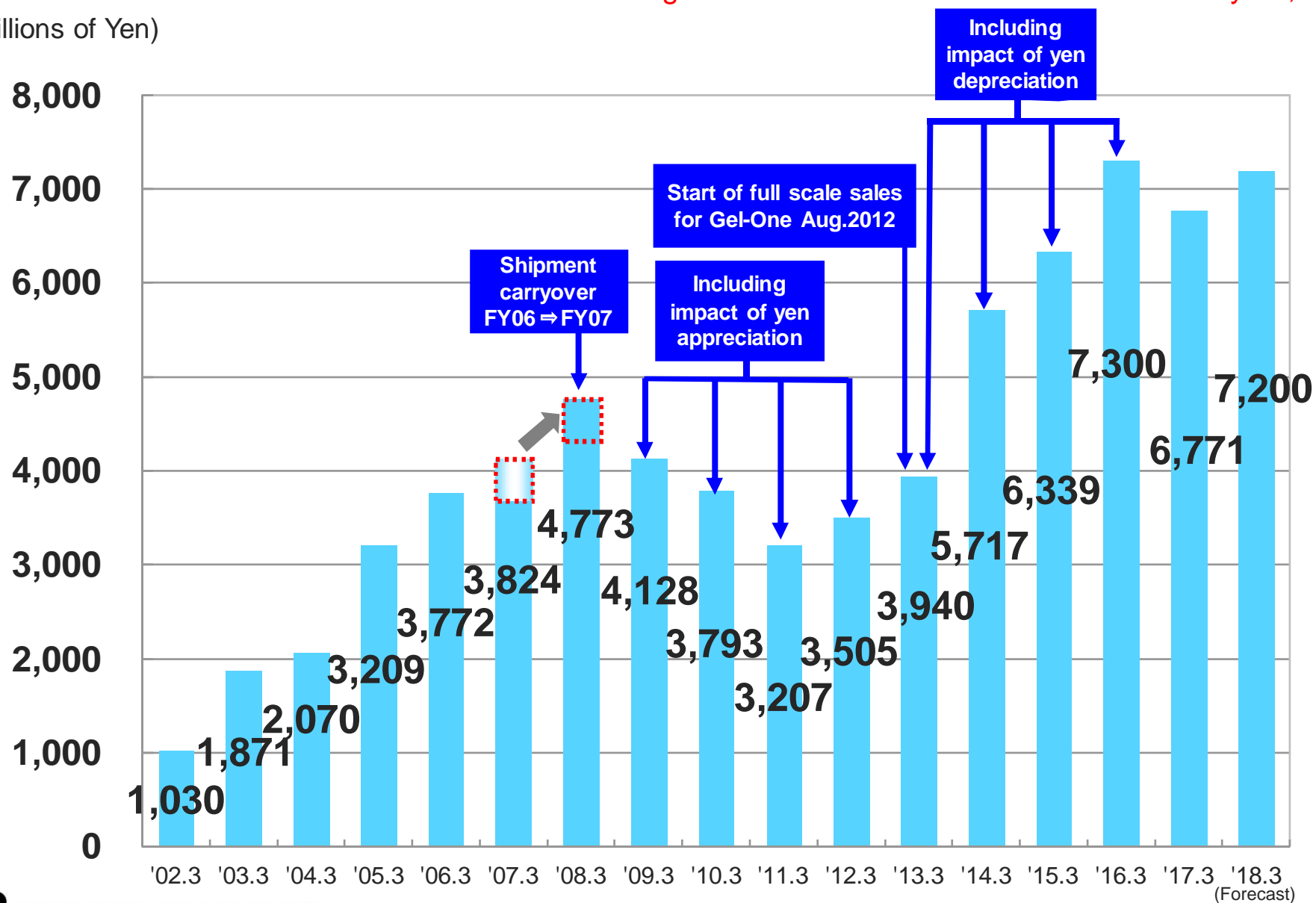


The OPEGAN series viscoelasticity comparison

Trend in Overseas Sales of Hyaluronic Acid Products

*No change from the results forecast announced May 12, 2017

(Millions of Yen)



U.S. Market for HA Products

Number of osteoarthritis patients (estimate)



Ratio of patients using HA products is approx.10% of patients receiving any treatment for osteoarthritis.
⇒ There is large room to expand.

HA products market (estimate)

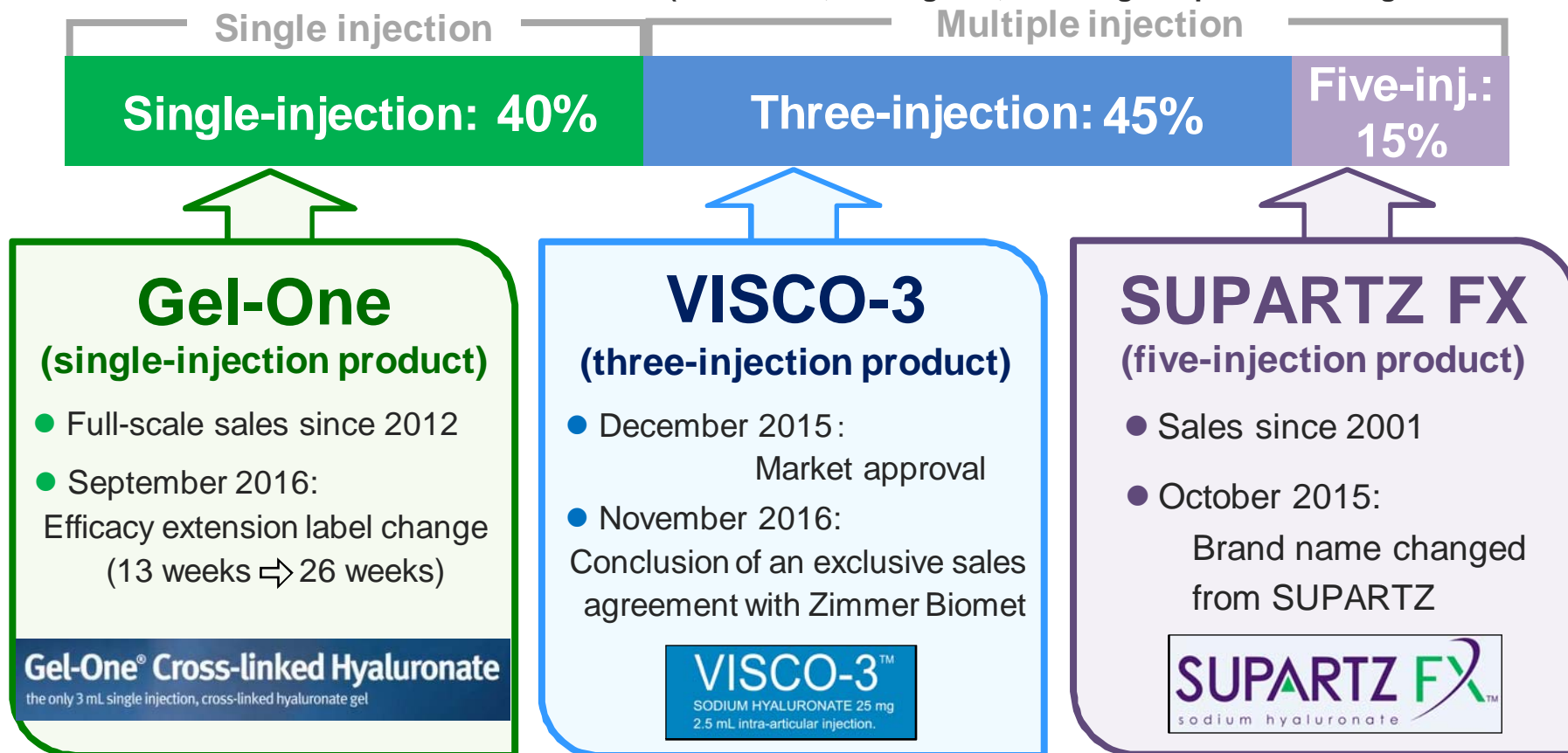


* Numbers in this slide are estimated by Seikagaku

Measures to Strengthen Product Presence in the U.S.

Product value enhancement and product line reinforcement as the leading company in the joint function improving agent field

■ U.S. market share by number of injections
 (value basis, 2016 figures, including competitors. Seikagaku estimates)



The LAL Business

What is the LAL business?

The manufacturing and sale of reagents used in the quality control of pharmaceuticals and in water quality Control in dialysis at hospitals

*Endotoxin detection reagents are reagents whose main ingredient is Limulus Amebocyte Lysate (LAL).

*Endotoxins are substances derived from bacteria. Since they cause fever even in minute amounts, testing for endotoxin contamination in pharmaceuticals is compulsory

➤ **Size of the global market: Approx. ¥25.0 billion**
(Seikagaku estimate, including associated equipment)



Endotoxin detection reagents
(for quality control of pharmaceuticals
and medical devices)

Associates of Cape Cod, Inc. (ACC)

- U.S. subsidiary of Seikagaku Corporation (established in 1974, acquired by Seikagaku in 1997)
- Developed the world's first endotoxin detection reagent and obtained FDA approval in 1977
- A sales network spanning 80 countries
- Solid business performance in recent years



PYROCHROME®



Exterior of the ACC offices

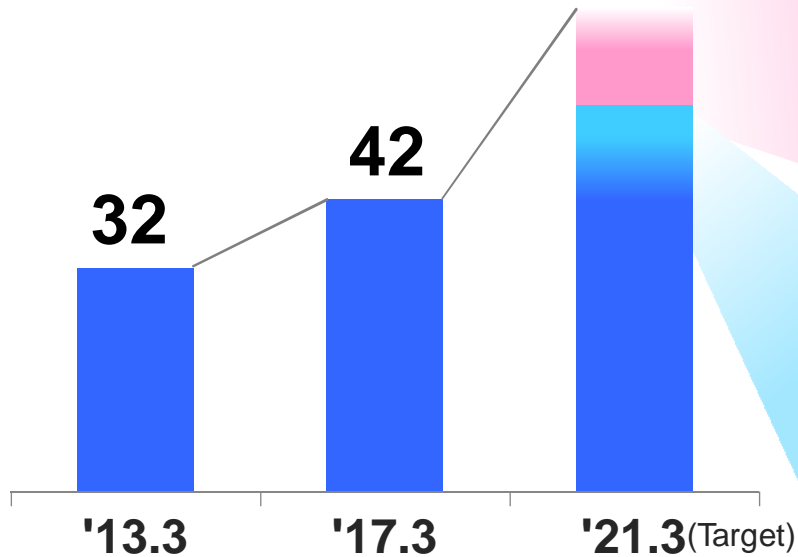
Growth Strategy for ACC (U.S. Subsidiary)



Acceleration of sales channel expansion at ACC, the core of the LAL Business

(Millions of US\$)

70 Mil\$ Plan



Sales trend and medium-term sales plan for ACC (U.S. subsidiary)

■ Opening up of new sales channels and new business sectors

- ✓ Opening up and expansion of new sales channels (Shift from selling through distributors to a direct sales structure)
- ✓ Collaborative business start-ups with partners from different industries

■ Strengthening of existing businesses

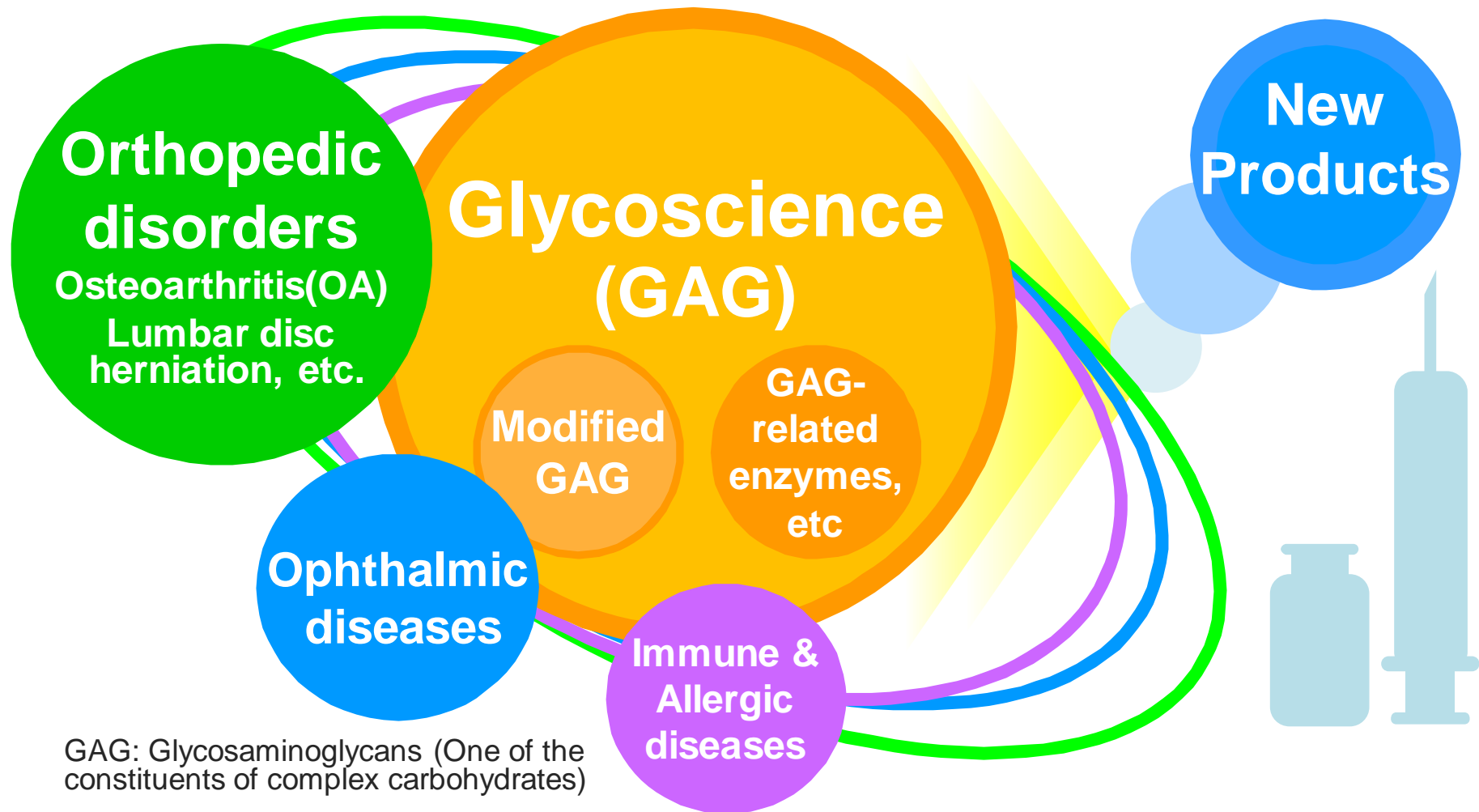
- ✓ Retaking of share from competitors through the introduction of new products and improved products
- ✓ Augmentation of sales capabilities through recruitment of sales representatives
- ✓ Expansion and enhancement of contract test services

LAL Business: The manufacturing and sales of endotoxin detection reagents and other products used in the quality control of pharmaceuticals and medical devices

ACC: Associates of Cape Cod, Inc. (U.S. subsidiary)

Basic Policy on Research and Development

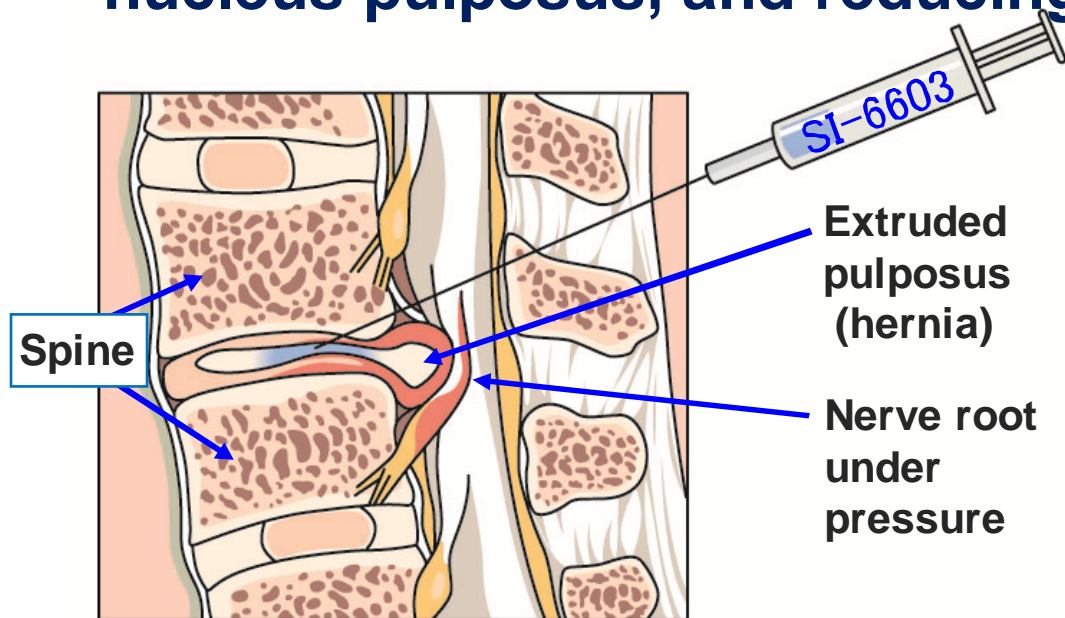
Aiming for the early, continuous introduction of new products that meet high treatment needs, focusing on glycoscience as an area of specialization



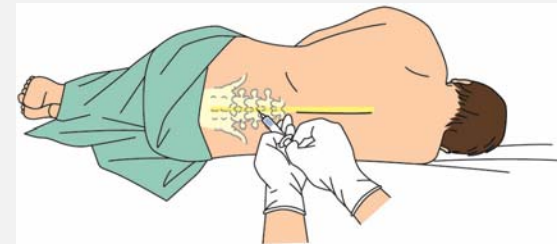
GAG: Glycosaminoglycans (One of the constituents of complex carbohydrates)

Outline of SI-6603 (Treatment for Lumbar Disc Herniation)

The purpose of SI-6603 is to relieve pain by specifically degrading GAGs (such as chondroitin sulfate), the main components of the nucleus pulposus, shrinking the herniated nucleus pulposus, and reducing the pressure on nerves



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



Expected Features:

- Single injection expected to relieve the pain of lumbar disc herniation
- Does not break down proteins, therefore no harmful effects on blood vessels, nerves, etc.
- Expected to reduce the physical burden on patients and contribute to QOL improvement

Agreement Status for SI-6603 (Treatment for Lumbar Disc Herniation)

**Exclusive overseas development and marketing rights
licensed to Ferring Pharmaceuticals**
**Planned receipt of milestone royalties of up to \$95 million
(of which, an down payment of \$5 million)**

Overseas: Ferring Pharmaceuticals (Switzerland)



SEIKAGAKU CORPORATION

- An R&D-driven biopharmaceutical group established in 1950
- Worldwide sales: approx. 2.0 billion euros (2016)
- August 2016: Conclusion of an exclusive worldwide (excluding Japan) license agreement



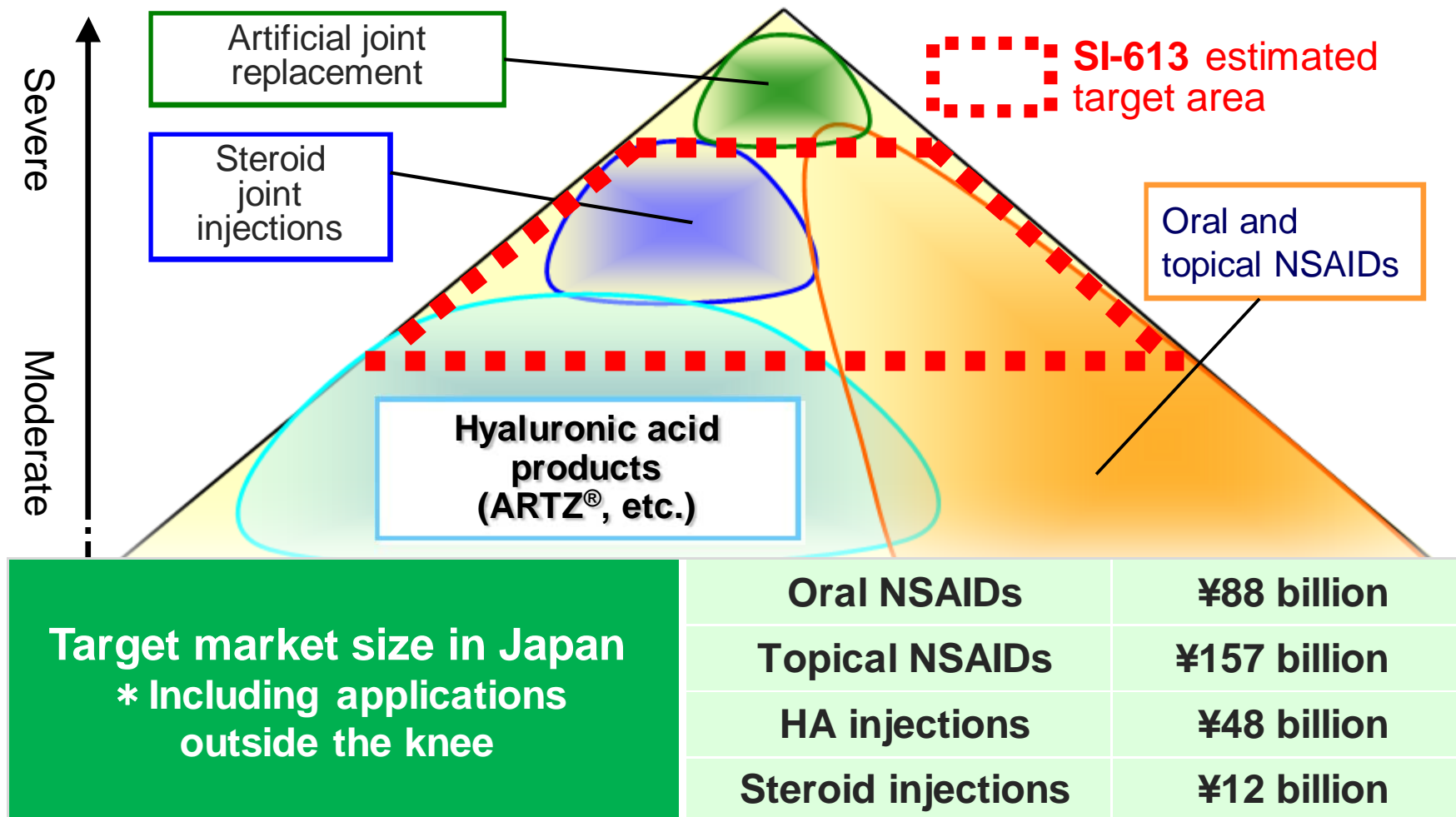
Ferring Pharmaceuticals headquarters
(Saint-Prex, Switzerland)

Japan: Kaken Pharmaceutical Co., Ltd.

- Sales partner for the joint function improving agent ARTZ
- December 2012: Conclusion of an exclusive distribution agreement in Japan

SI-613 Estimated Target Patients

Estimated patients with severe pain and being treated with oral or topical NSAIDs or intra-articular steroid injection



Contract Status by R&D Theme

Planned receipt of milestone royalties in accordance with future progress in development and marketing

Development Code Indication	Development Location	Sales Partner	Total Amount of Milestone Royalties (of which, in upfront payment)
SI-6603 Lumbar Disk Herniation	Japan	Kaken Pharmaceutical Co., Ltd.	Non-disclosure
	U.S.	Ferring Pharmaceuticals (Switzerland)	Max. US \$95 million (US \$5 million)
SI-613 Japan: Osteoarthritis U.S. : Knee Osteoarthritis	Japan	Ono Pharmaceutical Co., Ltd.	Max. ¥10.0 billion (¥2.0 billion)
	U.S.	Searching	—
SI-613-ETP Enthesopathy	Japan	Ono Pharmaceutical Co., Ltd.	*included in the above
SI-614 Dry eye	U.S.	Searching	—

Mid-term Management Plan (FY2016 to FY2018)

Ten-Year Vision “Global Category Pharma”

Focus research and development on glycoscience
establishes global competitiveness

【Final Step】

Achieving the Ten-Year Vision
and Making a Further Leap
Forward

Step 2

Cultivation of new leads
for achieving the Ten-Year Vision

2016-2018

Step 1

Cultivation of basic strength
and systems development

2012-2015

2009-2011

ACT for the Vision

Active spirit · Creative mind · Takeoff

Overcome severe environment in the business,
achieve the Ten-Year Vision, and
survive as a “Global Category Pharma”

Mid-term Management Plan: **Four High-Priority Strategies**

1.

Preparing for launch of SI-6603, a treatment for lumbar disc herniation

2.

Powering up as a leader in the knee osteoarthritis market

3.

Enhancement of the development pipeline

4.

Pursuit of an optimal production system

Achieving the Ten-Year Vision and Making a Further Leap Forward

Mid-term Management Plan: Numerical Targets

FY2018 Target

Net sales: ¥32.0 billion
Operating income: ¥2.5 billion
Ordinary income: ¥4.5 billion

《Key Assumptions of Numerical Targets》

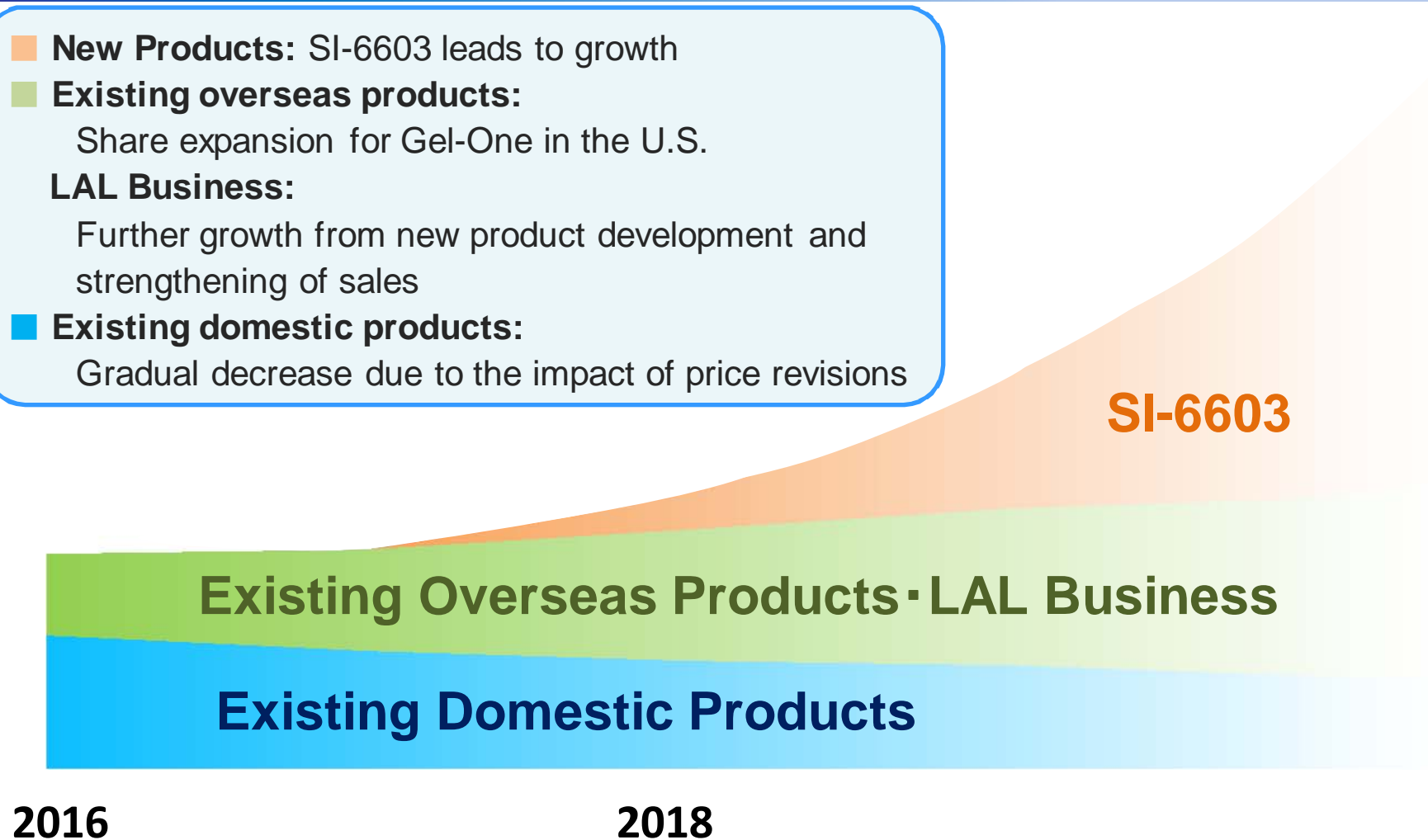
- Overseas business expansion to compensate for a decrease in revenue due to NHI drug price reductions in Japan (overseas sales ratio: 45%)
- A high level of R&D expenses (ratio of R&D expenses to net sales: 25% to 30%)
- Various royalty incomes as non-operating income
- Exchange rate: ¥110 to the U.S. dollar

**Achieving the Ten-Year Vision and
Making a Further Leap Forward**

Topics for Advancing to the Next Stage

(Schematic Representation of Growth)

- **New Products:** SI-6603 leads to growth
- **Existing overseas products:**
Share expansion for Gel-One in the U.S.
- **LAL Business:**
Further growth from new product development and strengthening of sales
- **Existing domestic products:**
Gradual decrease due to the impact of price revisions



**Achieving the Ten-Year Vision and
Making a Further Leap Forward**

Special Profile

1

Specialization in glycoscience

- Niche field, market not big enough for the major pharmaceutical companies to penetrate
- Focusing on this field more than **70 years**

2

Unique business model

- Concentration on **R&D** and **manufacturing**
- R&D staff comprising **one-third** of our total employees
- Allocation of **25% to 30%** of net sales to R&D investment

3

State-of-the-art technology related to GAG

- **Extraction, Purification, Fermentation**, etc. technology to manufacture GAG related products
- Drug discovery expertise using modified-GAG, GAG-related enzymes, etc.

Our Business Segment

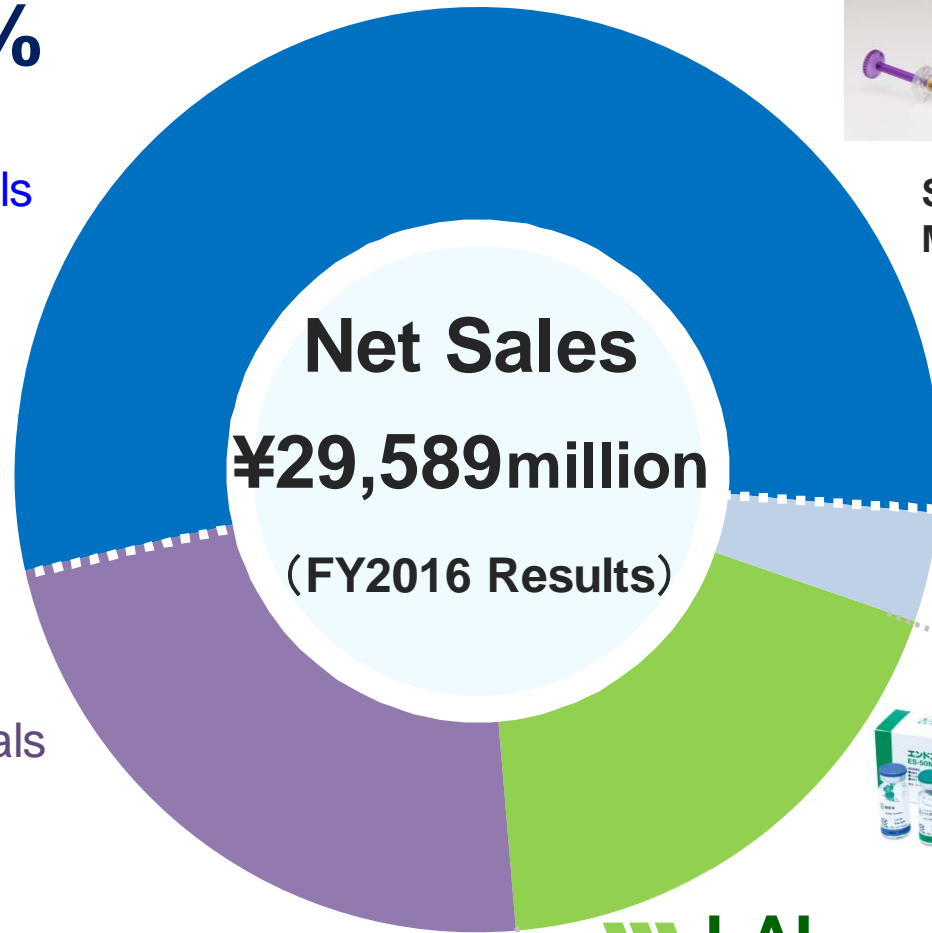
Pharmaceutical Business 81.6%

Domestic
Pharmaceuticals
⇒ 55.0%

Joint Function
Improving Agents



Overseas
Pharmaceuticals
⇒ 22.9%



Ophthalmic Surgical Aids



Surgical Aids for Endoscopic
Mucosal Resection



Bulk Products
⇒ 3.8%

Bulk Products



Endotoxin-detecting
reagents

(used mainly for quality
control of pharmaceuticals
and medical devices)

LAL Business 18.4%

Main Hyaluronic Acid (HA) Products

ARTZ® Knee osteoarthritis (OA) pain relief by multiple injections

- The first HA joint function improving agent in the world
- Main distributors:
 - Kaken Pharmaceutical (Japan): ARTZ®
 - Bioventus (U.S.): SUPARTZ FX™
 - Kunming Baker Norton Pharmaceutical (China): ARTZ®



Gel-One® Knee OA pain relief by a single injection

- Requires only 3ml to be as effective as multiple injections
- Full-scale sales since August 2012
- Distributor: Zimmer (U.S.)



Exploring the Innovative Promise of Glycoscience

■ **Cautionary Notes**

This material contains forward-looking statements regarding future management strategies or performance forecasts. These statements are based on judgments derived from information that is currently available to Seikagaku and are subject to risk and uncertainty. Actual results and developments may differ significantly from these forward-looking statements due to various factors.

Information about pharmaceutical products or medical devices (including products currently in development) included in this material is not intended to constitute an advertisement or medical advice.



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