Financial Results for the 2nd Quarter of Fiscal Year 2020

(April 1, 2020 – September 30, 2020)

SEIKAGAKU CORPORATION

(TSE:4548)

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< 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.

Overview for 2Q of FY2020

(Millions of Yen)	2Q FY2020 Results	Year-on-Year		(Reference) FY2020 Full Year Forecasts	
		Change	% of Change	FY 2020 Forecasts	Degree of Progress
Net sales	**13,533**	**-2,022**	**-13.0%**	**26,650**	**50.8%**
Operating Income	**718**	**-1,431**	**-66.6%**	**550**	**130.7%**
Ordinary Income	**1,098**	**-1,373**	**-55.6%**	**1,400**	**78.4%**
Net Income	**976**	**+11,742**	**—**	**1,150**	**84.9%**
R&D Expenses (Ratio to net sales)	**3,535** (26.1%)	**+527** (+6.8pt)	**+17.5%**	**7,400** (27.8%)	**47.8%**
Average Exchange Rate (1US$)	¥106.92	-¥1.71		2Q forecast ¥105.00	

	2Q FY2020 Results	2Q FY2019 Results	(Reference) FY2020 Forecasts
Net Income per Share	**¥17.30**	-¥190.86	¥20.38

Net sales by Business Segment (2Q of FY2020)

(Millions of Yen)	2Q FY2020 Results	Year-on-Year	% of Change
Net sales	13,533	-2,022	-13.0%
Pharmaceuticals	10,234	-2,002	-16.4%
Domestic Pharmaceuticals	6,278	-982	-13.5%
Overseas Pharmaceuticals	3,006	-1,433	-32.3%
Bulk Products /CDMO	948	+413	+77.1%
LAL Business	3,299	-20	-0.6%
(Overseas sales)	6,185	-1,030	-14.3%

＊ Foreign exchange impact on overall net sales ： approx. -85million yen

Domestic Pharmaceuticals

▶ ARTZ (Joint-function improving agent)

- Sales decreased, due to a shrinking market caused by NHI drug price reductions and a decrease in outpatient services accompanying the spread of COVID-19

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

▶ OPEGAN series (Ophthalmic viscoelastic devices)

- Sales increased, compensating for NHI drug price reduction as shipments rise due to impact of shipment adjustments for competing products

▶ MucoUp

(Submucosal injection agent for endoscopic surgery)

- Sales decreased due to offensive of low-cost pricing strategies for competing products and a decrease in surgeries during COVID-19

▶ HERNICORE

(Treatment for lumbar disc herniation)

- Sales decreased due to large shipments in the same period of the previous fiscal year

HERNICORE:
Japan's first treatment for lumbar disc herniation launched in August 2018

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Overseas Pharmaceuticals

*Foreign exchange impact on Overseas Pharmaceuticals: approx. -40 million yen

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

- Sales decreased due to lower shipments in 1Q
- Gradual easing of postponements for non-essential medical procedures due to COVID-19

Gel-One:
Intra-articular single-injection viscosupplement for the treatment of knee osteoarthritis

▶ SUPARTZ FX in the U.S. (Multiple injection)

- Sales decreased reflecting lower sales volume due to the continuing trend towards products requiring a low number of injections

▶ ARTZ in China (Multiple injection)

- Market is following a recovery trend
- Sales decreased due to adjustment of shipments to sales partner

Net sales by Business Segment (2Q of FY2020)

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Bulk Products / CDMO

- Sales increased shipments of bulk products, as well as the addition of sales from CDMO services at Dalton Chemical Laboratories, Inc.

＊Starting from the second quarter under review, the sales of Dalton Chemical Laboratories, Inc., which became a subsidiary in March 2020, are included in the pharmaceuticals business segment

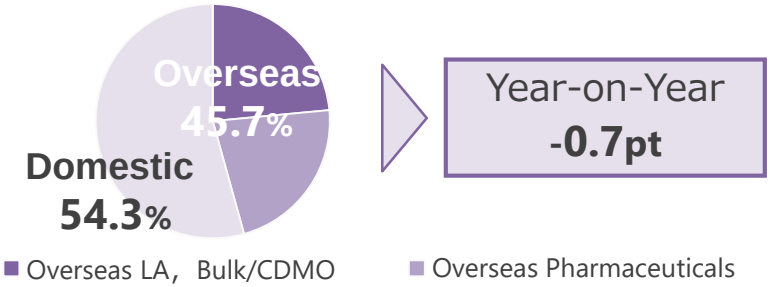
LAL Business

*Foreign exchange impact on LAL Business: approx. -45 million yen

- Sales steady were at the prior-year level due to growth in sales of Clinical Diagnostic (Fungitell) reagents, despite a decrease in sales of Bacterial Endotoxin Testing (BET) reagents
- COVID-19 infection to be limited at this time

＊LAL business: Manufacturing and sale of endotoxin-detecting reagents used in quality control for pharmaceuticals and medical equipment

Overseas Sales Ratio



Income for 2Q of FY2020 (Year-on-Year)

(Millions of Yen)	2Q FY2020 Results	Year-on-Year	% of Change
Net sales	13,533	-2,022	-13.0%
Cost of Sales (Cost of Sales ratio)	6,120 (45.2%)	-659 (+1.6pt)	-9.7%
SGA expenses	6,694	+69	+1.0%
R&D Expenses (to Net sales ratio)	3,535 (26.1%)	+527 (+6.8pt)	+17.5%
Operating Income (to Net sales ratio)	718 (5.3%)	-1,431 (-8.5pt)	-66.6%
Ordinary Income	1,098	-1,373	-55.6%
Extraordinary loss	—	+12,304	—
Net Income	976	+11,742	—
Depreciation	388	-1,063	-73.2%

Operating Income

Cost of Sales Ratio (+1.6pt)

- Cost of sales ratio up year-on-year as prior-year impairment loss on property, plant and equipment related to the pharmaceuticals business lowers depreciation, while NHI drug price reductions affect sales in Japan and a change in sales composition

SGA Expenses（+69）

- Decrease in operation expenses including sales promotion expenses (-439)
- R&D expenses increase due to costs of additional clinical study of SI-6603 in the U.S. (+527)

Ordinary Income

Non-operating Income / Expenses（+58）

- Royalty income increases (+90)
- Foreign exchange losses fall (+82)
- Decrease in gains on sales of investment securities (-166)

Net Income

Extraordinary loss

- Impairment loss recognized in prior-year period (+12,304)

Overview of Forecasts in FY2020

(Millions of Yen)	FY2020 Forecasts	FY2019 Results			(Reference) Degree of 2Q Progress
		Results	Change	% of Change	
Net sales	26,650	28,642	-1,992	-7.0%	50.8%
Operating Income	550	1,960	-1,410	-71.9%	130.7%
Ordinary Income	1,400	3,981	-2,581	-64.8%	78.4%
Net Income	1,150	-10,839	+11,989	–	84.9%
R&D Expenses (Ratio to net sales)	7,400 (27.8%)	6,877 (24.0%)	+522 (+3.8pt)	+7.6%	47.8%
Average Exchange Rate (1US$)	2Q forecast ¥105.00	¥108.75			

	FY2020 Forecasts	FY2019 Results
Net Income per share	¥20.38	¥-192.15
Dividend per share	¥20.00	¥26.00
Dividend Payout ratio	98.1%	–

Exchange Rate Sensitivity (Impact of a change of ¥1against the US$)	
Net sales	Approx. ¥120 million
Operating income	Approx. ¥35 million

Forecasts (Net sales) in FY2020

(Millions of Yen)	FY2020 Forecasts	Year-on-Year	
		Change	% of Change
Net sales	26,650	-1,992	-7.0%
Pharmaceuticals	20,250	-1,916	-8.6%
Domestic Pharmaceuticals	12,100	-1,579	-11.5%
Overseas Pharmaceuticals	6,300	-1,166	-15.6%
Bulk Products /CDMO	1,850	+830	+81.4%
LAL Business	6,400	-76	-1.2%
(Overseas sales)	12,800	-113	-0.9%

＊ Foreign exchange impact on overall net sales ： approx. -250million yen

Net sales

- Projecting lower sales due to the impact of NHI drug price reductions in Japan in addition to the worldwide outbreak of COVID-19

＊ Foreign exchange impact on overall net sales ： approx. -250million yen

Pharmaceuticals

Domestic Pharmaceuticals：
Lower sales from NHI drug price reductions and effects of shrinking market due to COVID-19

Overseas Pharmaceuticals：
Despite a recovery trend for local sales in 2Q, the impact of the large decline in sales volume in 1Q will lead to lower sales for the full year

Bulk Products/CDMO：
Sales up after adding in contract development and manufacturing organization

LAL Business

- Generally in line with the prior-year level period given the limited impact from COVID-19

Forecasts (Income) in FY2020

(Millions of Yen)	FY2020 Forecasts	Year-on-Year Change	Year-on-Year % of Change
Net sales	**26,650**	**-1,992**	**-7.0%**
Operating Income (Ratio to net sales)	**550** (2.1%)	**-1,410** (-4.7pt)	**-71.9%**
Ordinary Income	**1,400**	**-2,581**	**-64.8%**
Extraordinary loss	**—**	**+13,524**	**—**
Net Income	**1,150**	**+11,989**	**—**
Cost of Sales ratio	**44.3%**	**+0.6pt**	**—**
R&D Expenses (Ratio to net sales)	**7,400** (27.8%)	**+522** (+3.8pt)	**+7.6%**
Depreciation	**800**	**-978**	**-55.0%**

Operating Income

Cost of sales ratio（+0.6pt）：

- A small increase affected by COVID-19 impact and NHI drug price reductions in Japan as well as lower depreciation due to prior-year impairment losses

SGA Expenses（approx. +100）：

- Operating expenses down as a result of a review of costs related to sales promotion campaigns (approx. -600)
- Additional R&D expenses from the recruitment of subjects for additional clinical studies of SI-6603 in the US (approx. +500)

Ordinary Income

Non-operating Income / Expenses：

- Forecasting lower royalty income

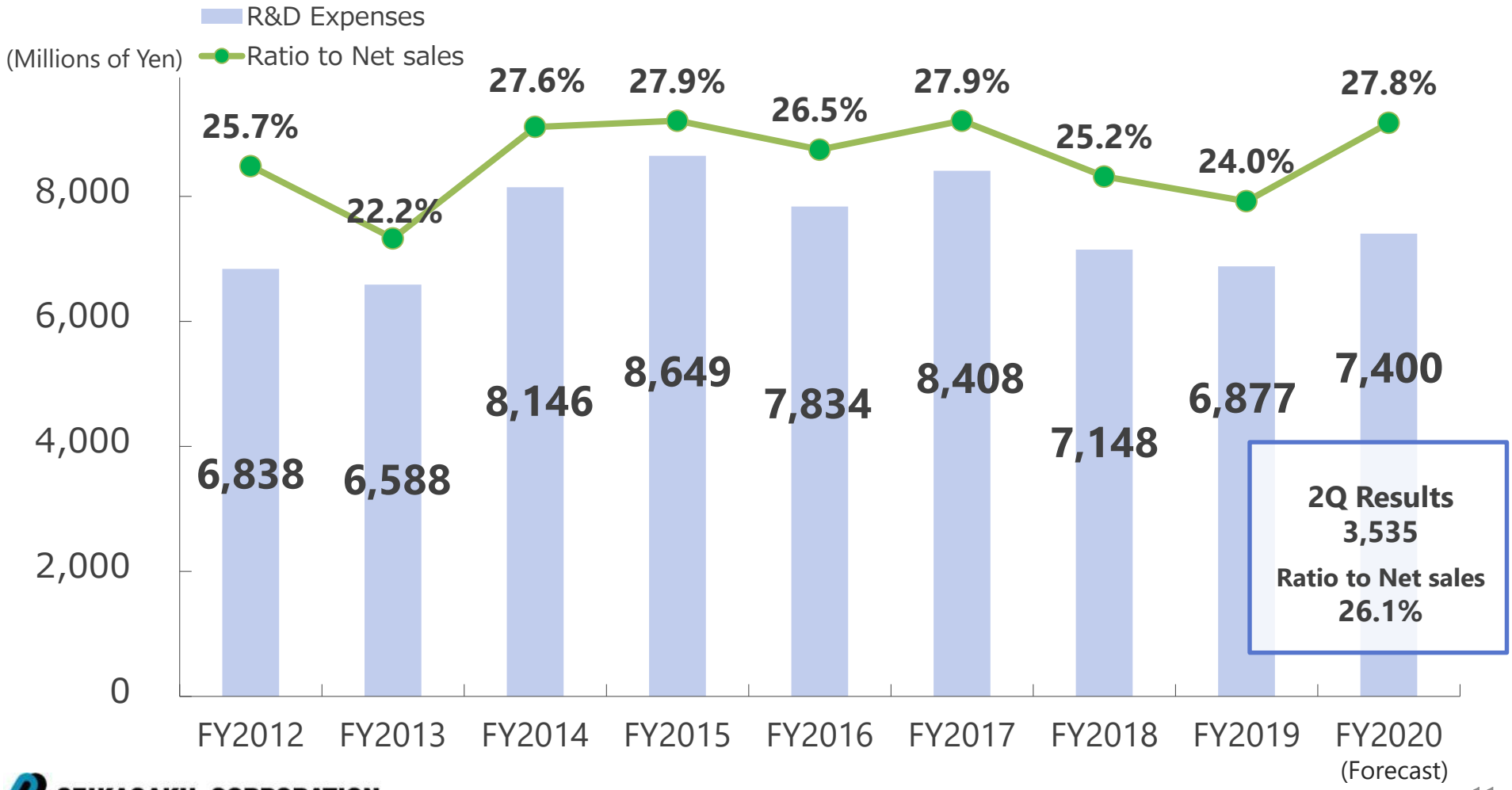
Net Income

Extraordinary loss：

- Prior-year impairment losses on property, plant and equipment related to the pharmaceuticals business (+13,524)

Trend in R&D Expenses

Continuing to focus on drug discovery specializing in Glycoscience
Undertaking improvement in R&D efficiency



Domestic Pharmaceuticals (Unit deliveries to medical institutions/Year-on-Year)

ARTZ（Joint-function improving agent）

● **2Q FY2020 Results**
- Market contracts from a drop in outpatient services due to COVID-19

▶ **FY2020 Forecasts**
- Planning to expand share by promoting switching from competing products (growth rate: -4.8% / Market share: 61.5%)

growth rate：-8.0%
Market growth rate：-10.1%
Market share ：60.7%
（+1.3pt）

OPEGAN（Ophthalmic viscoelastic devices）※including SHELLGAN

● **2Q FY2020 Results**
- Market contracts in conjunction with fewer surgeries due to COVID-19
- Added volume and share due to shipment adjustments for competing products

▶ **FY2020 Forecasts**
- Aiming for additional expansion through promotion of switching from competing products (growth rate:+8.4% / Market share: 57.9%)

growth rate：+5.6%
Market growth rate：-13.7%
Market share ：54.2%
（+9.9pt）

HERNICORE （Treatment for lumbar disc herniation）

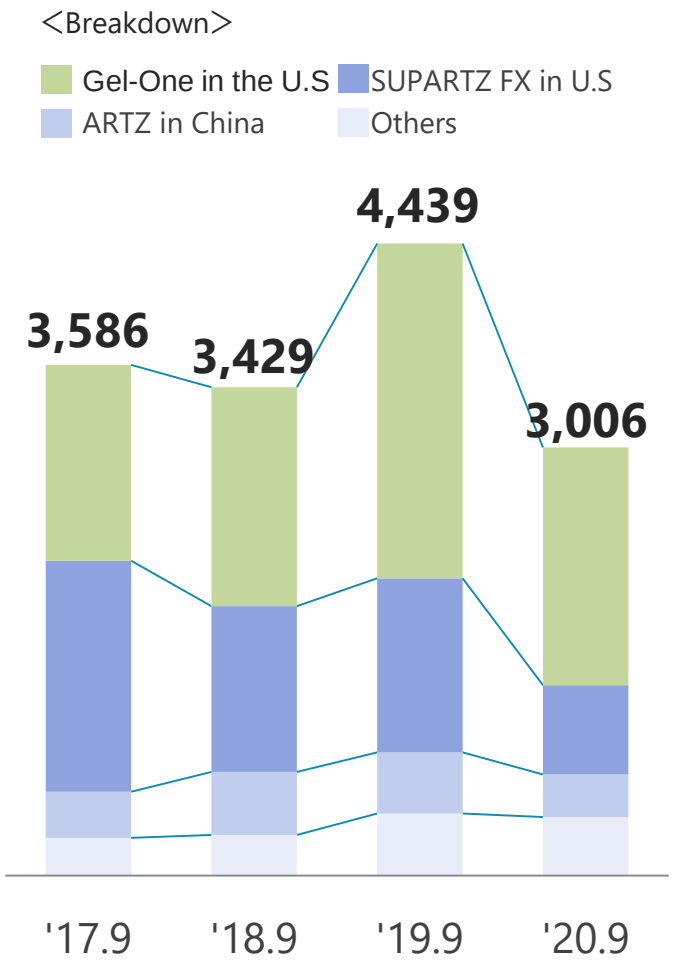
● **2Q FY2020 Results**
- Increased deliveries to medical institutions due to the addition of new user facilities

▶ **FY2020 Forecasts**
- Flat year-on-year as projected treatment opportunities fall due to COVID-19 infection while number of facilities for deliveries grow

Overseas Pharmaceuticals (2Q FY2020 Results Year-on-Year / value basis)

Overseas Pharmaceuticals Sales trend

(Millions of Yen)



2Q FY2020 Results
-32.3%

Market on a mild uptrend
Sales down due to shipment adjustments for COVID-19 and by Chinese sales companies

U.S.

●U.S. Market

- A recovery trend marked by a market contraction due to COVID-19 and a slight easing of postponements for non-essential medical procedures since June
- A continuing trend towards products requiring a low number of injections

● Sales in the U.S.

Gel-One : Increase due to market recovery (+5% volume-based)
Due to successful to switch from competing products and market expansion in single injection products, trending above prior year since June

SUPARTZ FX : Sales down as trends continue towards selection of products requiring a low number of injections

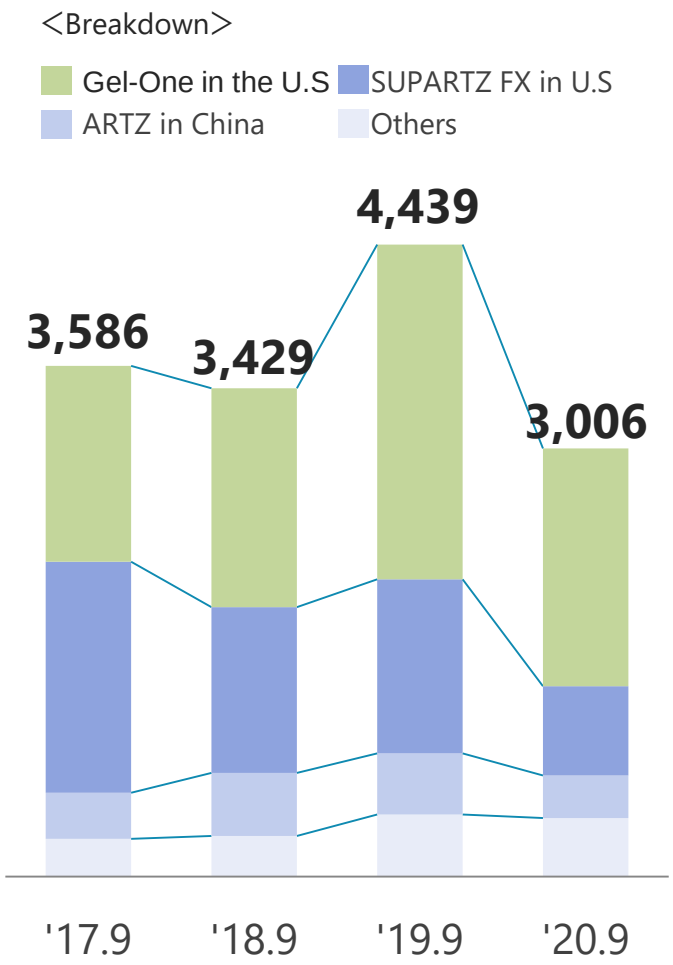
▶ Seikagaku exports

An overall decline driven by lower Gel-One sales due to low 1Q shipments and decreased local sales of SUPARTZ FX

Overseas Pharmaceuticals (2Q FY2020 Results Year-on-Year / value basis)

Overseas Pharmaceuticals Sales trend

(Millions of Yen)



2Q FY2020 Results
-32.3%

Market on a mild uptrend
Sales down due to shipment adjustments for COVID-19 and by Chinese sales companies

China, Other Regions

● China Market

An overall return to normal despite suppression of outpatient services since April in some regions

● Local sales of ARTZ in China

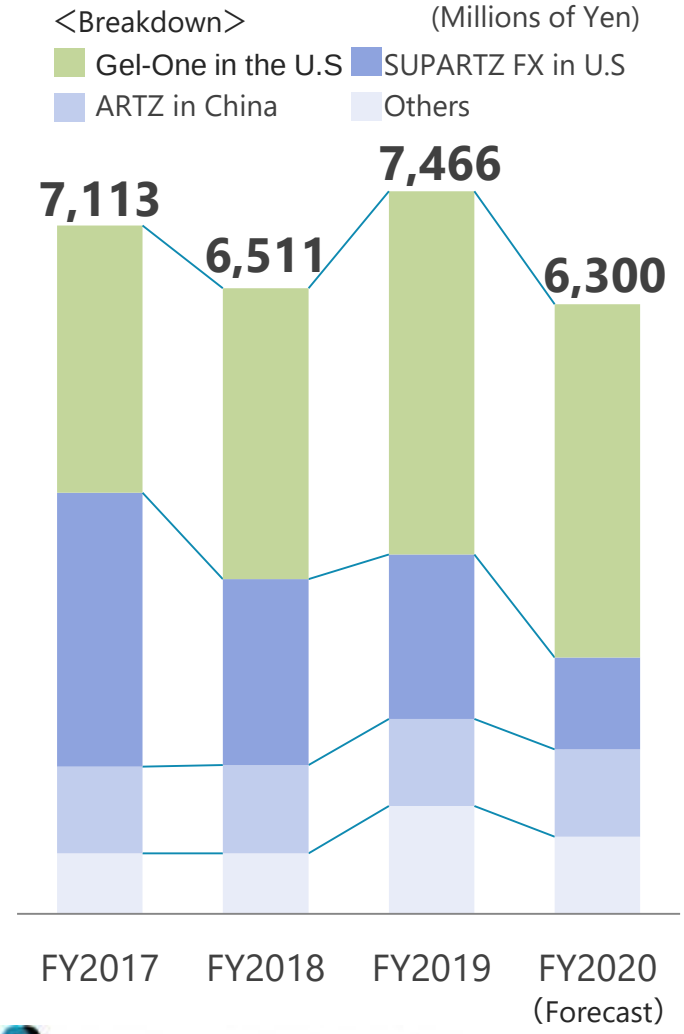
Market on a recovery towards prior-year levels

▶ Seikagaku exports

Seikagaku sales down on adjusted shipments to distributors of ARTZ in China
Seikagaku sales decline marked by a lack of recovery for local outpatient services in Italy

Overseas Pharmaceuticals (FY2020 Forecast Year-on-Year / value basis)

Overseas Pharmaceuticals Sales trend



FY2020 Forecast
-15.6%

Forecasting a major decline owing to 1Q effects despite a market trend towards recovery

U.S.

- **Sales in the U.S.**
  - **Gel-One：** Increase due to measures to switch from competing products (+5% volume-based)
  - **SUPARTZ FX：** Ongoing decrease from greater severity of market

▶ **Seikagaku exports**

Sales declined at Gel-One, which is unable to offset the portion lost through decreased shipments in 1Q
SUPARTZ FX sales decline due to a drop-off in local sales

China, Other Regions

- **Local sales of ARTZ in China**

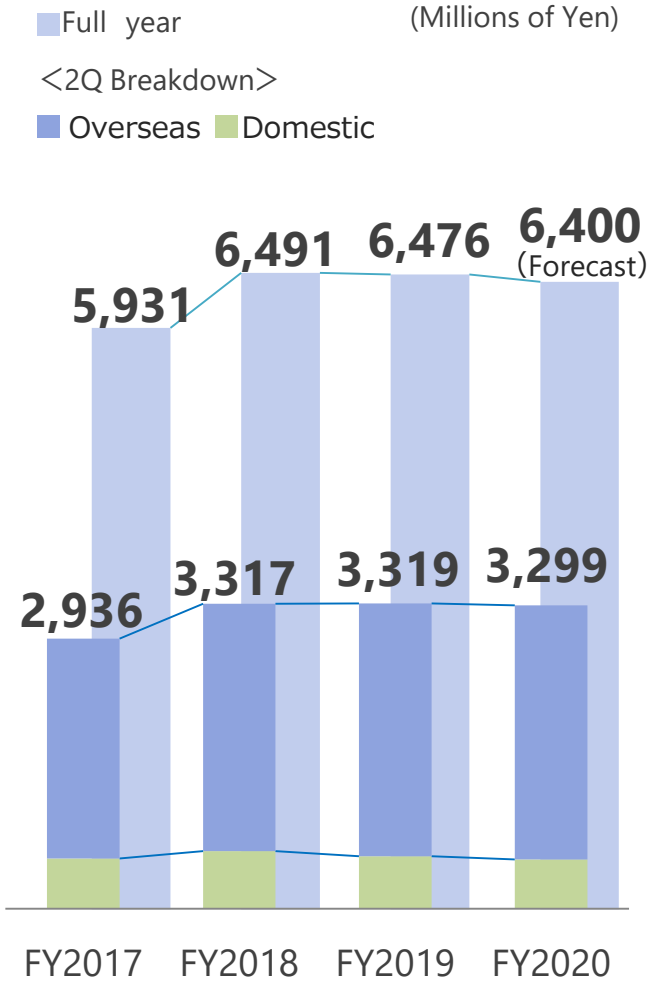
A sales increase from a return to market normal

▶ **Seikagaku exports**

Italy a large decrease
China and Taiwan largely in line with last year

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

LAL Business Sales trend



2Q FY2020 Results : - 0.6% (Year-on-Year)

Overseas

＊Foreign exchange impact: approx. - ¥50million

Flat year-on-year as Bacterial Endotoxin Testing (BET) reagents had lower sales, while Clinical Diagnostic (Fungitell) reagents had sales growth

Domestic

A decline due to large sales of other reagents in the previous year

FY2020 Forecasts : -1.2% (Year-on-Year)

Overseas

A flat outlook despite some impact on sales activities by COVID-19 infection

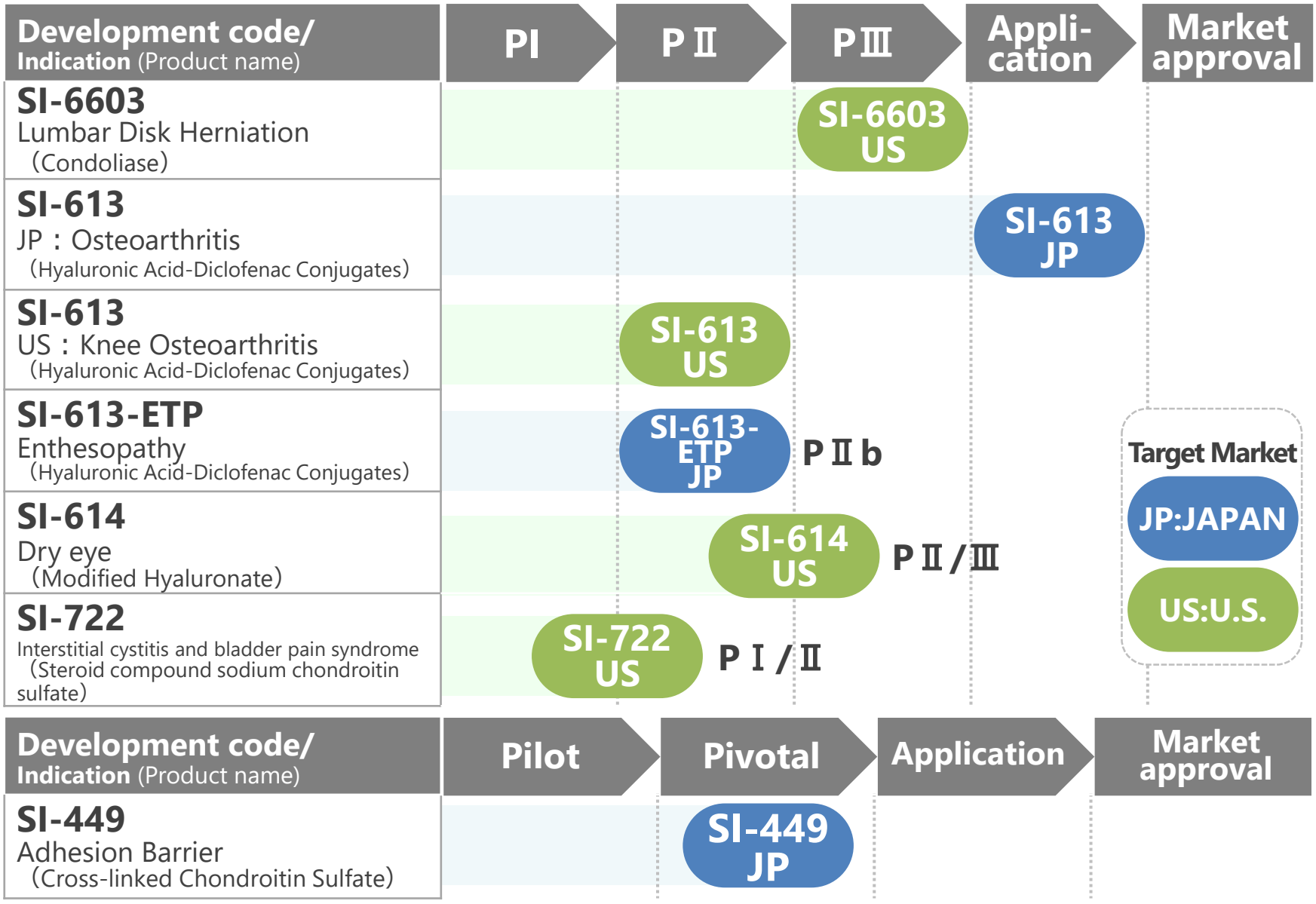
Domestic

Lower sales due to a change in equipment delivery periods as a result of COVID-19

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

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

Pipeline List (Research and Development themes)



SI-6603 (Treatment for Lumbar Disc Herniation)

Expecting delays owing to the COVID-19 infection, but making steady progress in enrolling subjects at each facility

Development status

▶**Additional Phase III study in the U.S.** Intiated February 2018.
Extending enrollment by two years, aiming for November 2022 completion

⇒**Delay of anticipated due to the spread of COVID-19**

- Impacted by discontinuation of the study at some medical institutions and subjects postponing hospital visits
- Possibility of a further delay if a lockdown is ordered in a state where many trial sites are located

⇒**We plan to minimize delays as utilization rates at treatment facilities have been on a recovery since July**

- **Implement effective advertising campaigns to recruit subjects**
- **Advance early start-up of treatment facilities connected with local CROs**

Measures to promote enrollment

➢ Increase number of subjects

- Advertising suited to treatment facility requirements
- Strengthen coordination with medical institutions and increase patient introductions
- Relax enrollment standards

➢ Increase trial facilities

- Link-up with support vendors specializing in facility selection to increase number of facilities

SI-613 (Treatment of Osteoarthritis)

Responding to NDA review in Japan (osteoarthritis)
Scientific societies announce Phase III clinical study results

SI-613 (osteoarthritis) Japan

▶**Submitted a new drug application ("NDA") for manufacturing and marketing approval in Japan, for the treatment of osteoarthritis in January 2020**

NDA based on the results of the following three Phase III clinical studies conducted in Japan

1) Knee confirmatory study :
Demonstrated statistically significant improvement in a primary endpoint compared with a placebo

2) Study for four sites (four joint sites: shoulder, elbow, hip, and ankle):
Met a primary endpoint in patients with osteoarthritis of the hip joint and ankle joint

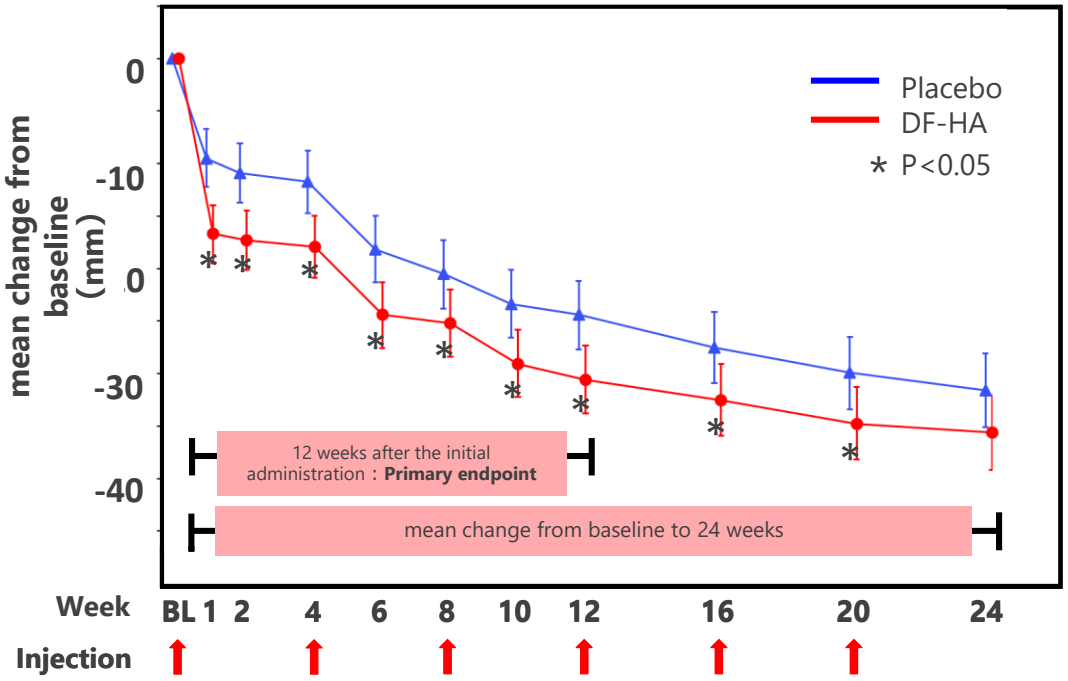
3) Long-term administration study:
No major safety concerns identified in any osteoarthritis patients

▶ **Scientific societies announce results of Phase III clinical studies in Japan**

- **The 93rd Annual Meeting of the Japanese Orthopaedic Association (held online from June 11 to August 31, 2020)**
  ⇒Results announced for Phase III clinical study in Japan for patients with knee osteoarthritis
- **The 33rd Annual Meeting of the Japanese Clinical Orthopaedic Association (held online from September 16 to October 23, 2020)**
  ⇒Results announced for Phase III clinical study in Japan for patients with knee osteoarthritis and long-term studies in Japan (two research papers) on administration in patients with osteoarthritis

SI-613 (Treatment of Osteoarthritis)

On the WOMAC A (pain) score, the primary endpoint, a statistically significant difference is recognized between the placebo group



	Placebo (n=220)	DF-HA (n=218*)
mean change from baseline to 12 weeks：Primary endpoint		
mean change from baseline	-17.1 [-19.8, -14.4]	-23.2 [-25.9, -20.4]
difference	-6.1 [-9.4, -2.8]	
P value	<0.001	
mean change from baseline to 24 weeks		
mean change from baseline	-20.8 [-23.6, -18.0]	-26.4 [-29.2, -23.6]
difference	-5.6 [-9.1, -2.2]	
P value	0.001	

least square mean [The 95% confidence interval]
Mixed model for repeated measures analysis
*FAS：Except for two cases with no effectiveness results after administration

※ DF-HA：Hyaluronic Acid-Diclofenac Conjugates（SI-613）

Source：The 93rd Annual Meeting of the Japanese Orthopaedic Association
The phase III study of Diclofenac etalhyaluronate (ONO-5704/SI-613) in osteoarthritis of the knee

SI-613 (Treatment of Osteoarthritis)

Entered into an agreement with Eisai for a marketing alliance in South Korea
Alliance with a second country following China

SI-613 (osteoarthritis of the knee) U.S.

▶Analysis of Phase II clinical study results is complete
Proceeding with partner selection in parallel with examination of Phase III study

SI-613 (osteoarthritis of the knee) China

▶Agreement with Eisai on a co-development and marketing alliance in China, in April 2020
Proceeding with preparation of a clinical development plan

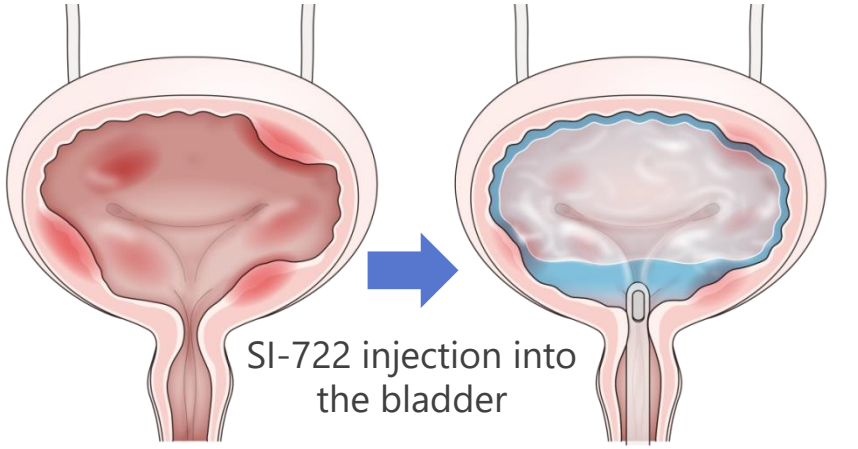
SI-613 (osteoarthritis of the knee) South Korea

▶Agreement with Eisai for a market alliance
Aims to obtain approval by South Korea of the clinical study data and approval content in Japan
Plans to apply for South Korean approval following the obtaining of approval by Japan

SI-722 (Treatment of Interstitial cystitis and bladder pain syndrome)

Restarting operations at all treatment facilities with aims to shorten delays related to COVID-19

SI-722 Administration image



Development status

▶ **U.S. Phase I/II / Starting November 2019**

- **Started subject administration in March 2020**
  - **⇒Plans delayed by COVID-19 effects**
  - **⇒Operations restarting at all treatment facilities Study underway with priority placed on infection prevention**

Promising features

▶ Designed for sustained release by bonding steroids to chondroitin sulfate

▶ Anti-inflammatory effects of steroids under sustained release should provide sustainable relief of frequent urination and bladder pain

<SI-722 summary>

Dev. Code : SI-722 Generic name : Steroid conjugated with chondroitin sulfate

Indication : Interstitial cystitis and bladder pain syndrome

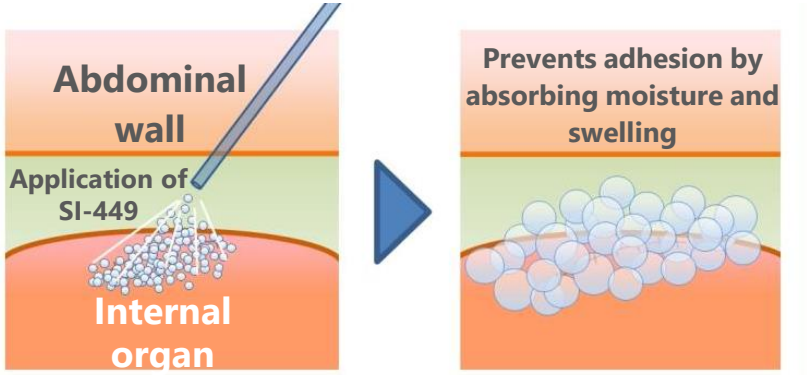
Method of use : Injection into the bladder

Estimated U.S. patients : 1.3 million (Seikagaku estimates)

SI-449 (Adhesion Barrier / Medical Device)

Pivotal study started in May 2020
Delays caused by effects from COVID-19

SI-449 Administration image



Development status

- ▶ **Japan pivotal study / Starting May 2020**
  - **Evaluated for effectiveness, safety, and usability**

  ⇒Plans delayed by restrictions on visits to facilities due to COVID-19 effects

  ⇒ Treatment countermeasures in progress under a remote set-up
- ▶ Proceed with development with a view to global development; Start of U.S. pilot study under review

Promising features

- ▶ Leveraging pulverized characteristics to respond to healthcare needs through the spreading use of laproscopic surgery

<SI-449 summary>
Dev. Code ：SI-449 Generic name ： Cross-linked chondroitin sulfate
Product name ：Adhesion barrier
Method of use ：Intra-abdominal application (powdered formulation)
Adhesion barrier market：Japan: ¥13 billion, Global: ¥100 billion (Seikagaku estimates)

Basic Policy on Profit Distribution

Investing for substantial profit growth and raising corporate value, implementing business performance-linked dividends

Shareholder returns

- Setting a basic policy on linking dividends to financial performance
  FY2019：keeps in place its forecast for dividend distributions of ¥26 per share
  FY2020 & 2021：in consideration of business profits, it aims for a dividend payout ratio of 50%
- Examining the purchase of company treasury stock when appropriate

Business investment

- Investing efficiently in R&D and production facilities etc. for creating new value

Strategic investment

- Carrying out initiatives for strategic investments with prospects for future growth and synergy effects

	FY2016	FY2017	FY2018	FY2019	FY2020 (Forecast)
Net Income per share	¥31.55	¥69.30	¥39.76	¥-192.15	¥20.38
Annual Total Dividend	¥31.00※	¥26.00	¥26.00	¥26.00	¥20.00
Dividend Payout Ratio	98.3%	37.5%	65.4%	—	98.1%

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

Appendix

Response to the COVID-19 Infections

Measures to prioritize assurance of safety for employees and related parties

Production

- Establishing minimum operations to ensure production continuity at the Kurihama and Takahagi plants to bear complete responsibility for stable supply
- Ensuring sufficient inventories of raw materials, other materials, and hygienic materials; request made for standing purchasing arrangements
- Securing appropriate product inventories given the market trends
- Production continuity at overseas subsidiary

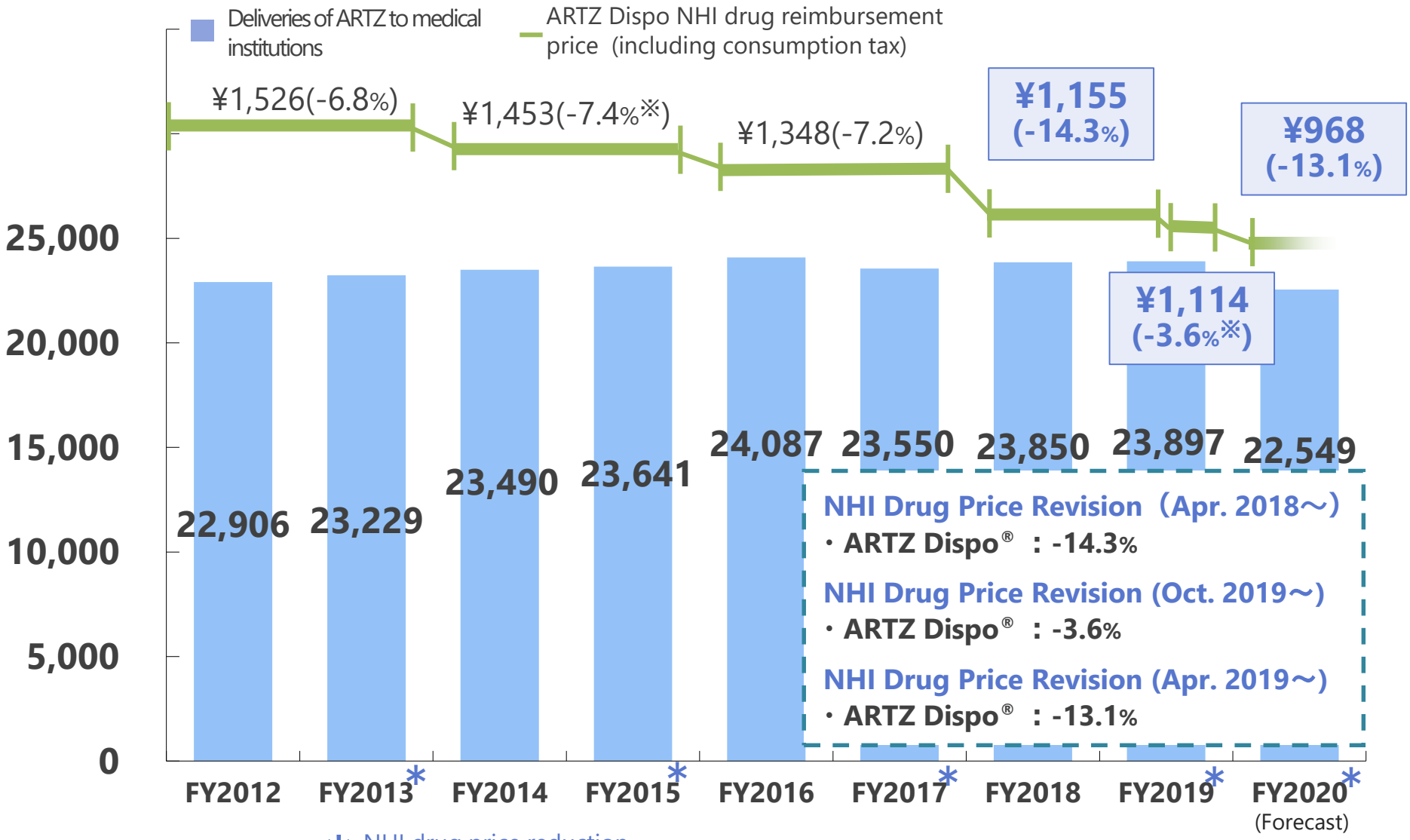
R&D

- In Japan and the US, clinical trials at some medical institutions were interrupted and subjects have missed their clinic visits, creating delays in the trials' progress.
- Infection prevention for patients and medical personnel in clinical trials are considered sufficient, and trials are being conducted to the extent possible according to the wishes of the trial facilities

Seikagaku's actions

- Launch an emergency headquarters for the response, develop infection control measures for employees and their families; for business continuity, build out a system in which essential work can be executed
- Supply masks and other PPE to medical facilities

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



* NHI drug price reduction
Extraordinary drug price revision in FY2019 accompanying a consumption tax increase (October 2019)　※ excluding the impact of consumption tax hike

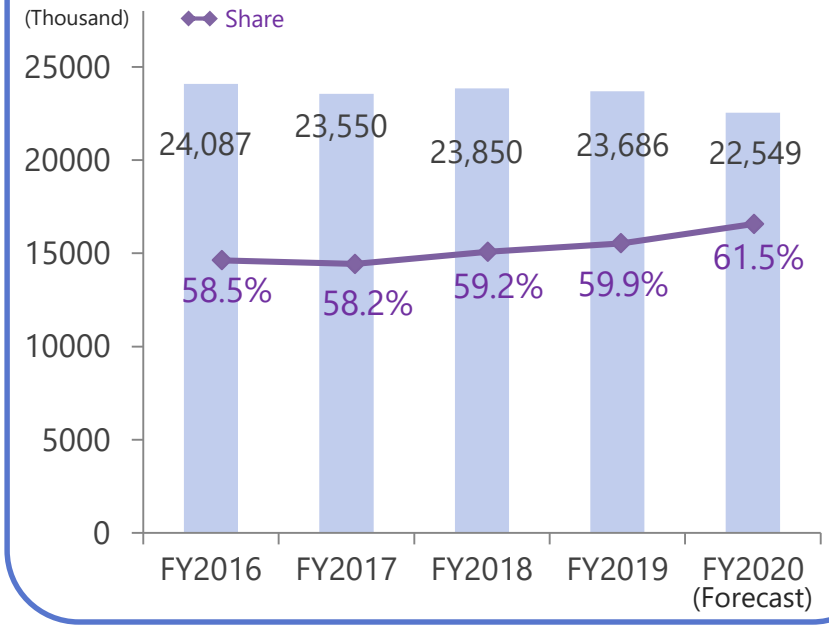
Trend in Deliveries of ARTZ / OPEGAN to Domestic Medical Institutions

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



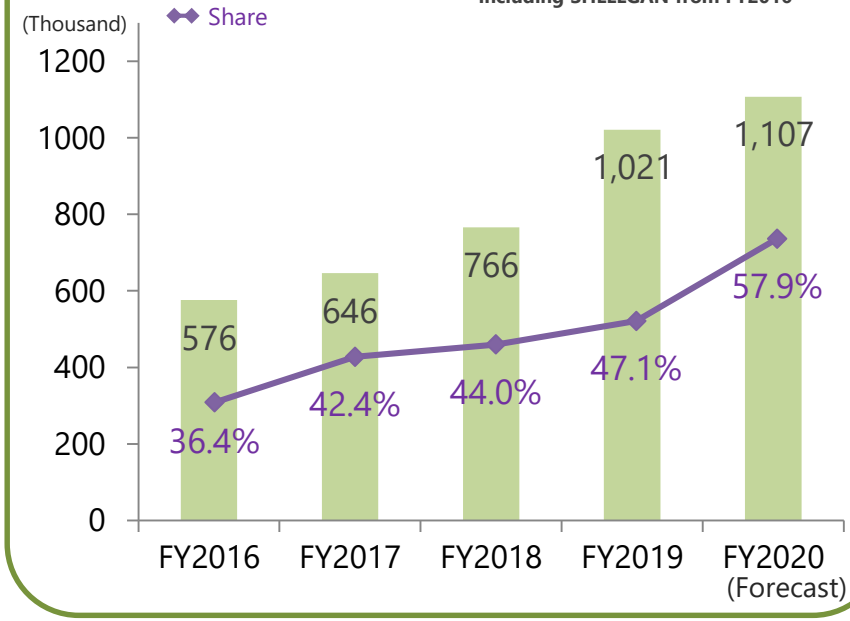
Ophthalmic viscoelastic devices

OPEGAN

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

Trend in unit deliveries to medical institutions

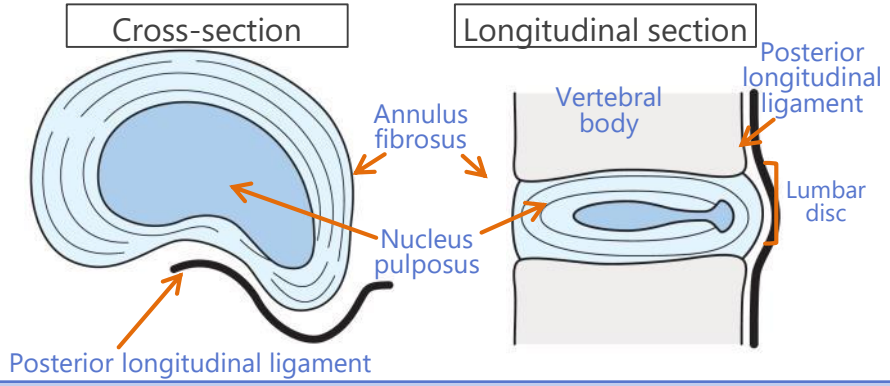
*Including SHELLGAN from FY2016



Four types of lumbar disc herniation

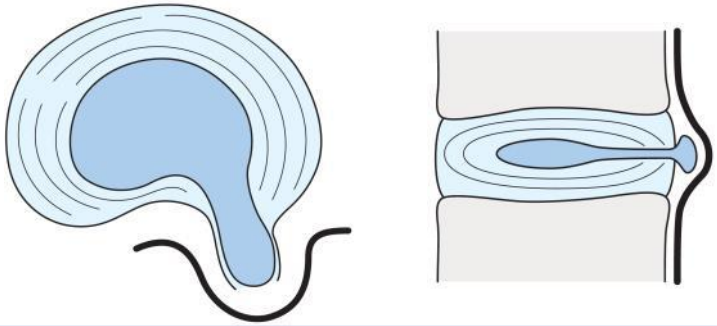
1. Protrusion

The hernia does not extend beyond the outermost layer of the annulus fibrosus



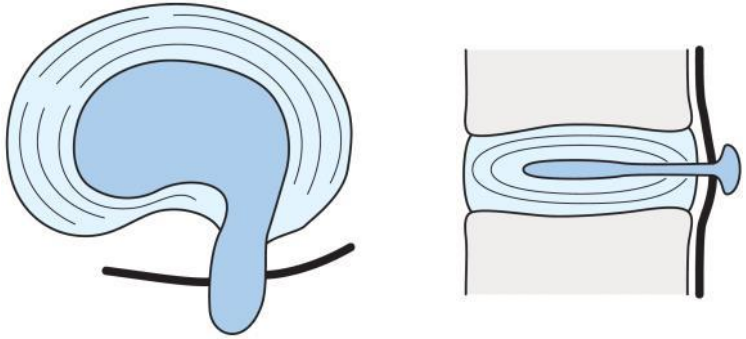
2. Subligamentous extrusion

Although the hernia extends beyond the outermost layer of the annulus fibrosus, it is covered by the posterior longitudinal ligament



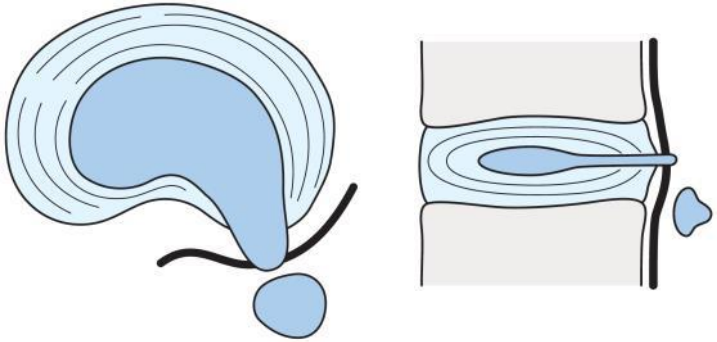
3. Transligamentous extrusion

The hernia perforates the posterior longitudinal ligament



4. Sequestration

The hernia migrates outside the dura mater



Post-marketing of HERNICORE in Japan

Promoting appropriate use and expanding opportunities for use; Firming up usage as new treatment options

- Coordinating with Kaken Pharmaceutical **engaging in information provision activities to ensure appropriate use and safety** through seminars with scientific societies and local workshops
- **Collecting pertinent information (post marketing surveillance)** with emphasis on safety information
- **Raising patients' recognition through awareness campaigns on the ailment**
- **Gradually expanding available physicians and facilities** through a review of requirements
(expecting moderate growth)

・ November 2019
Non-fulltime work facilities of supervisory physicians of the JSSR

・ April 2019
Physicians of the Neurospinal Society of Japan ＊[2]

・ August 2018
Physicians of the Japanese Society for Spine Surgery and Related Research (JSSR) *[1]

Roll-out to scientific societies
Requirements review
Adding facilities, etc.

Physician requirements

※1 ① Supervisory physicians or certified physicians of the Japanese Society for Spine Surgery and Related Research (JSSR) or who are supervised under the JSSR, or who participated in the this clinical study
②Physicians having experience with performing intradiscal puncture or at least 50 surgeries for lumbar disc herniation

※2 ① Supervisory physicians or certified physicians of the Neurospinal Society of Japan
②Physicians having experience with performing intradiscal puncture or at least 50 surgeries for lumbar disc herniation

Physician and Facilities Requirements for HERNICORE Use

Setting of physician and facility requirements for HERNICORE use to promote appropriate use and ensure safety

【 Physician requirements 】

【Japanese Society for Spine Surgery and Related Research】
: Physicians under the following conditions（as of April 2019）

1. Supervisory physicians or certified physicians of the Japanese Society for Spine Surgery and Related Research (JSSR) or who are supervised under the JSSR, or who participated in the this clinical study
2. Physicians having experience with performing intradiscal puncture or at least 50 surgeries for lumbar disc herniation

【 Neurospinal Society of Japan 】: Physicians under the following conditions（as of April 2019）

1. Supervisory physicians or certified physicians of the Neurospinal Society of Japan
2. Physicians having experience with performing intradiscal puncture or at least 50 surgeries for lumbar disc herniation

【Facility requirements】: Facilities under the following conditions

1. Facilities equipped with an X-ray fluoroscopic system (C-arm, etc.) capable of administering HERNICORE using clean technique
2. Facilities capable of treating shock and anaphylaxis
3. Facilities capable of performing urgent spine surgery or facilities that cooperate with facilities capable of performing spine surgery
4. Facilities with hospitalization equipment

※ Among those who meet the physician requirements, supervisory physicians in the JSSR may be used at non-fulltime work facilities that meet the facilities requirements (as of November 2019)

We plan to review these requirements with the consent of PMDA* approximately six months to one year after launching, following collection and careful examination of post-marketing safety information etc.

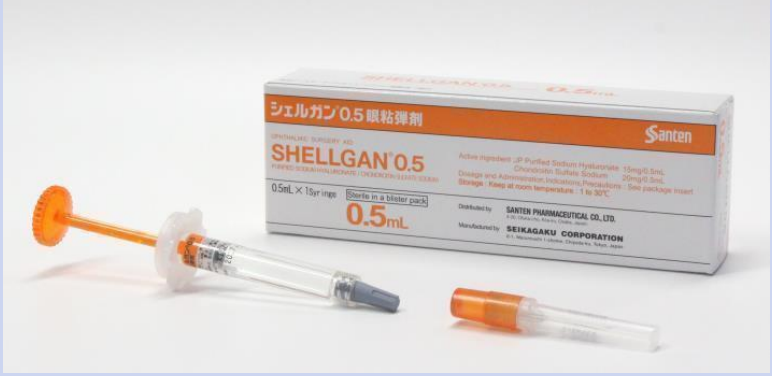
*PMDA: Pharmaceuticals and Medical Devices Agency

Ophthalmic viscoelastic devices SHELLGAN

眼科手術補助剤　薬価基準収載

シェルガン®0.5眼粘弾剤

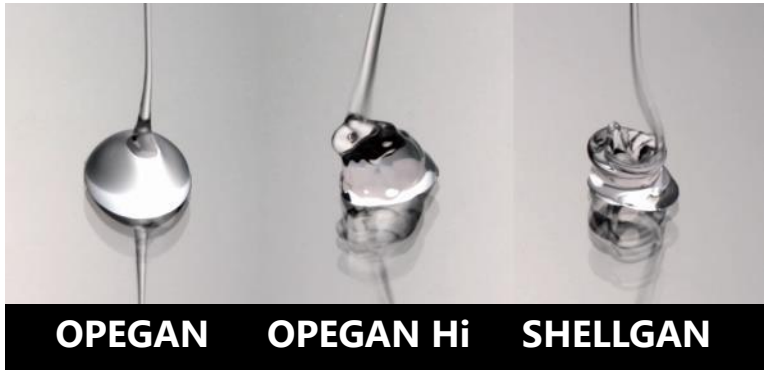
精製ヒアルロン酸ナトリウム/コンドロイチン硫酸エステルナトリウム



■ Product SHELLGAN Outline

- 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

Market Situation of Hyaluronic Acid Products in the U.S.

Market size of US$1,000 mil. in 2019 (-6.5% year-on-year)

■ **U.S. market share by number of injections** (Value basis, including competitors)

single-injection product
Gel-One

- Full-scale sales since 2012
- September 2016:
  Efficacy extension label change
  (13weeks⇒26weeks)

Gel-One® Cross-linked Hyaluronate
the only 3 mL single injection, cross-linked hyaluronate gel

three-injection product
VISCO-3

- December 2015：
  Market approval
- November 2016:
  Conclusion of an exclusive sales agreement with Zimmer Biomet

VISCO-3™
SODIUM HYALURONATE 25 mg
2.5 mL intra-articular injection.

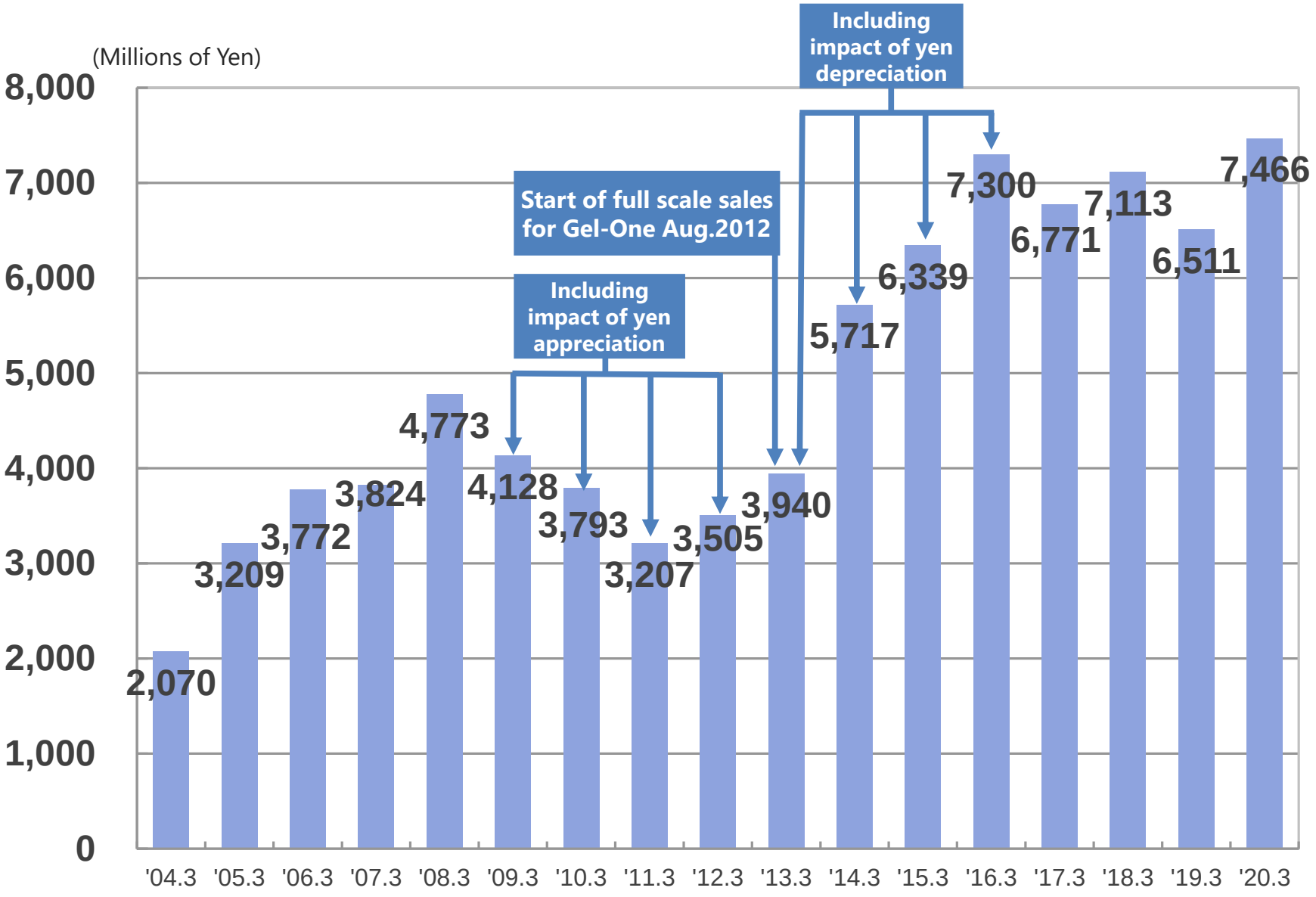
five-injection product
SUPARTZ FX

- Sales since 2001
- October 2015:
  Brand name changed from SUPARTZ

SUPARTZ FX™
sodium hyaluronate

*Figures for 2019, Seikagaku estimates

Trend in Overseas Sales of Hyaluronic Acid Products



The LAL Business

What is the LAL business?

The manufacturing and sale of reagents used in the quality control of pharmaceuticals, medical devices, biopharmaceuticals,
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 regulatorily required by certain jurisdictions

▶Size of the global market: Approx. ¥25.0 billion

(Seikagaku estimate, including required equipments)

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

Associates of Cape Cod, Inc. （ACC）

- U.S. subsidiary of Seikagaku
(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 over 80 countries
- Strong revenue growth in recent years

PYROCHROME®

Exterior of the ACC offices

Progress Against the Mid-Term Management Plan in Fiscal 2019

Ⅰ. Accelerating new drug discovery to become the pillar of new profits

- SI-613 (osteoarthritis): Submitted a new drug application for manufacturing and marketing approval (Jan 2020)
- SI-722: US Phase I/II clinical study started (Nov 2019)
- SI-449 pivotal study begins (May 2020)
- Enhancing R&D system to respond quickly to changing environments

Ⅱ. Solidifying the profit foundation through market expansion of new products

- SI-613: Concluded an agreement for a co-development and marketing alliance in China with Eisai (April 2020)
- HERNICORE: Use in Japan at facilities without full-time supervisory physicians accredited by the JSSR became possible (Nov 2019)

Ⅲ. Productivity improvement reforms

- Dalton added as a subsidiary (March 2020)
- implementing a cost review as a result of a cost reduction project

Solidifying our foundation in order to lay out a path for revived growth
Initiating various measures towards accelerated expansion and early realization

Outline of Acquisition

Dalton, a Canadian CDMO, becomes a subsidiary Acquiring a pharmaceuticals manufacturing base compliant with US/Canadian GMP

Outline of acquisition

- Name：Dalton Chemical Laboratories, Inc.
- Acquisition cost：Up to CAD 41 million
- Acquisition method：Acquired all issued shares

Dalton Chemical Laboratories, Inc.

- Location：Toronto, Ontario Province, Canada
- Established：1986
- Business description：
  Contract manufacturing services (CDMO*), including the manufacturing of chemosynthesis products and active pharmaceutical ingredients (API) and API process development for pharmaceutical companies
- Employee number：117

Exterior of the Dalton offices

＊CDMO：Contract Development and Manufacturing Organization
A business that supplies comprehensive services in drug development and manufacturing to pharmaceutical companies, including contract drug manufacturing, pharmaceutical formulation planning at the development stage, manufacturing of investigational drugs, and optimization of manufacturing conditions.

Synergistic effects of making Dalton a subsidiary

Accelerating new drug discovery and advancing production optimization and efficiency

Seikagaku
Specialized in new drug development & manufacturing

- Glycoscience R&D ability
- Final formulation technology and know-how in pharmaceuticals and medical devices

Dalton
Technology prowess related to CDMO

- Advanced technical skills in chemosyntheis
- Know-how in investigational drug manufacturing and process development
- Overseas GMP-certified

Synergies between the two companies

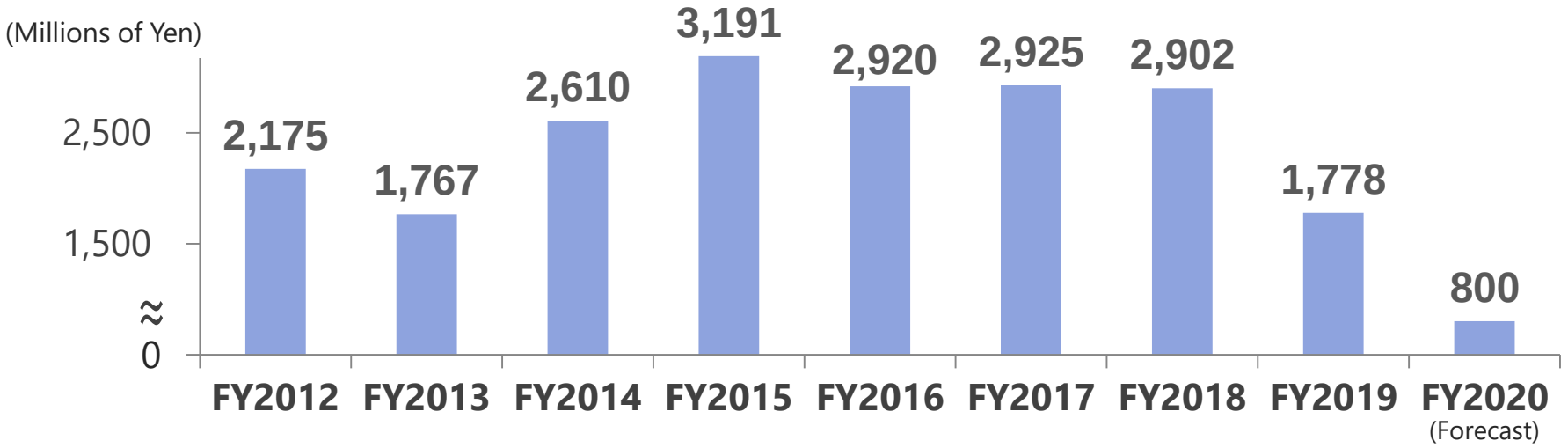
➢ **Seikagaku**
- Accelerating drug discovery (applying Dalton technology)
- In-house development of chemosynthesis products used in R&D, etc.
- Production optimization and efficiency improvements

➢ **Dalton**
- Business expansion by contracting from Seikagaku
- Developing a final formulation business

Trends in Depreciation & Capital Investments

Impairment loss taken in FY2019
Depreciation will trend toward ¥1.0 billion

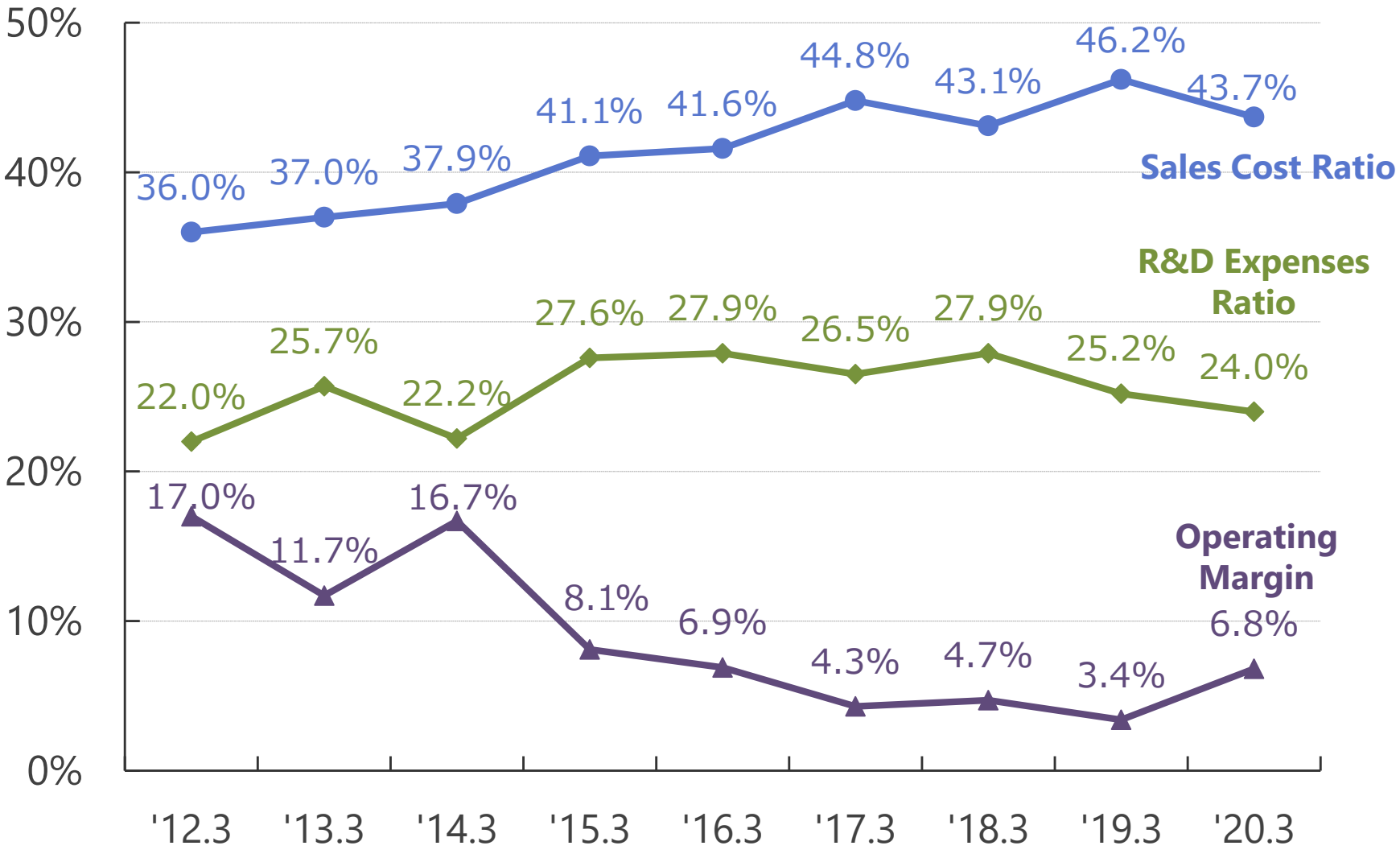
■ Trend in Depreciation



■ Trend in Capital Investments (Millions of Yen)

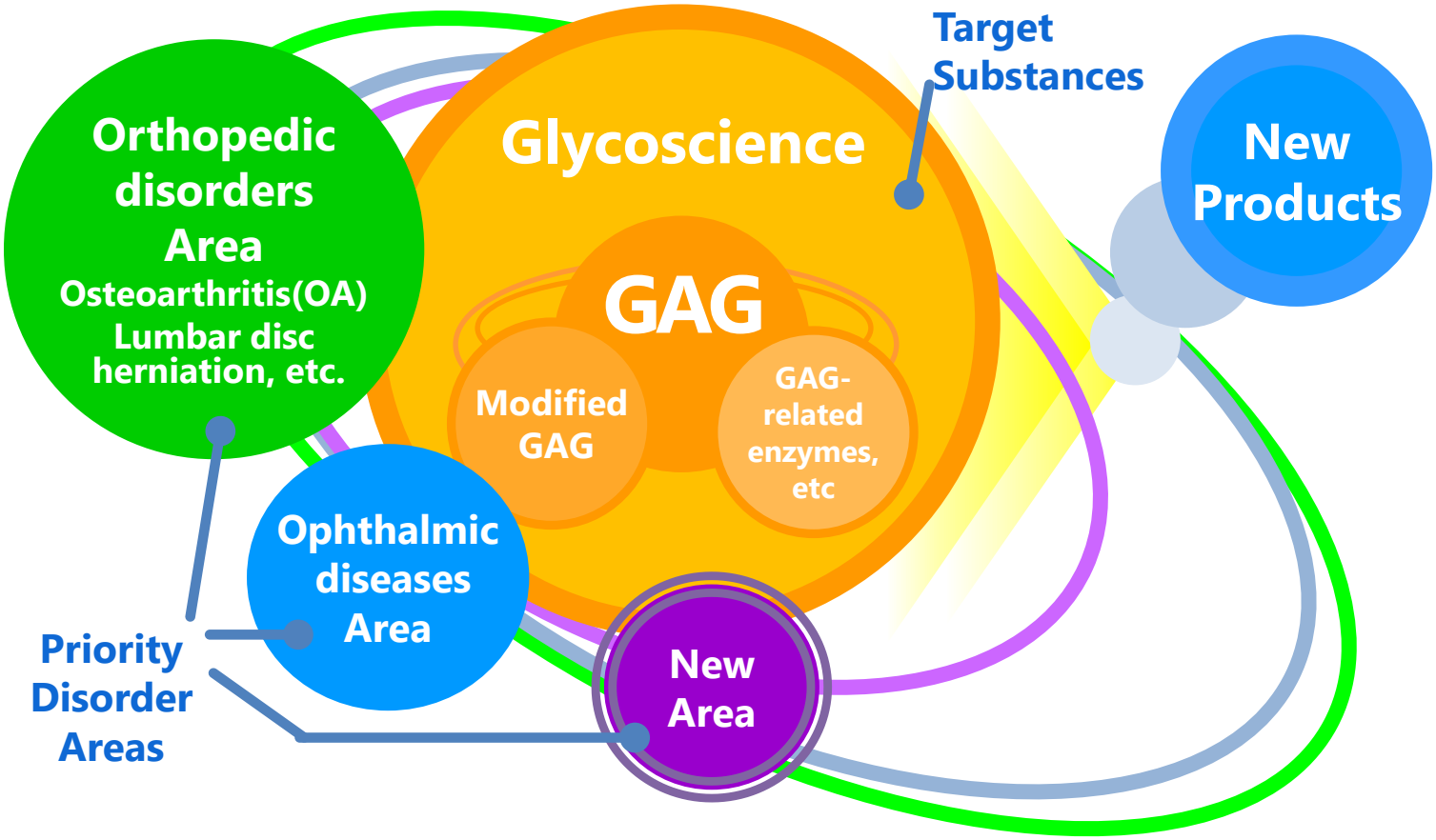
FY2012	FY2013	FY2014	FY2015	FY2016	FY2017	FY2018	FY2019	FY2020 (Forecast)
9,164	7,222	2,095	1,975	1,173	1,591	1,310	2,109	2,300

Trend in Financial Index



Basic Policy on Research and Development

Continue Our R&D policy to make the most of our technology and knowledge



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

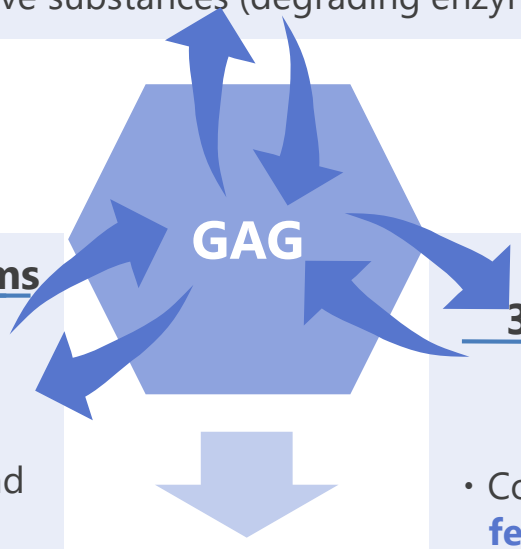
Strengthening and Making Use of The Company's Own GAG-related Core Technology

Accelerating R&D by leveraging our innovative drug discovery technology

1. Developing drugs through modification, processing, and bioactivity

- GAG **photo-cross-linking and chemical-cross-linking**
- **Physio-chemical functions** including viscoelasticity and retention
- Bioactive substances (degrading enzymes)

Gel-One
HERNICORE
SI-449



2. Applying drug delivery systems (DDS)

- **Support and delivery of** active pharmaceutical ingredients
- Expanding the lineup of supportable and deliverable drugs
  (low molecular→medium molecular→cells)
- DDS technology highly adaptable to general use (establishing drug discovery techniques)

SI-613
SI-722

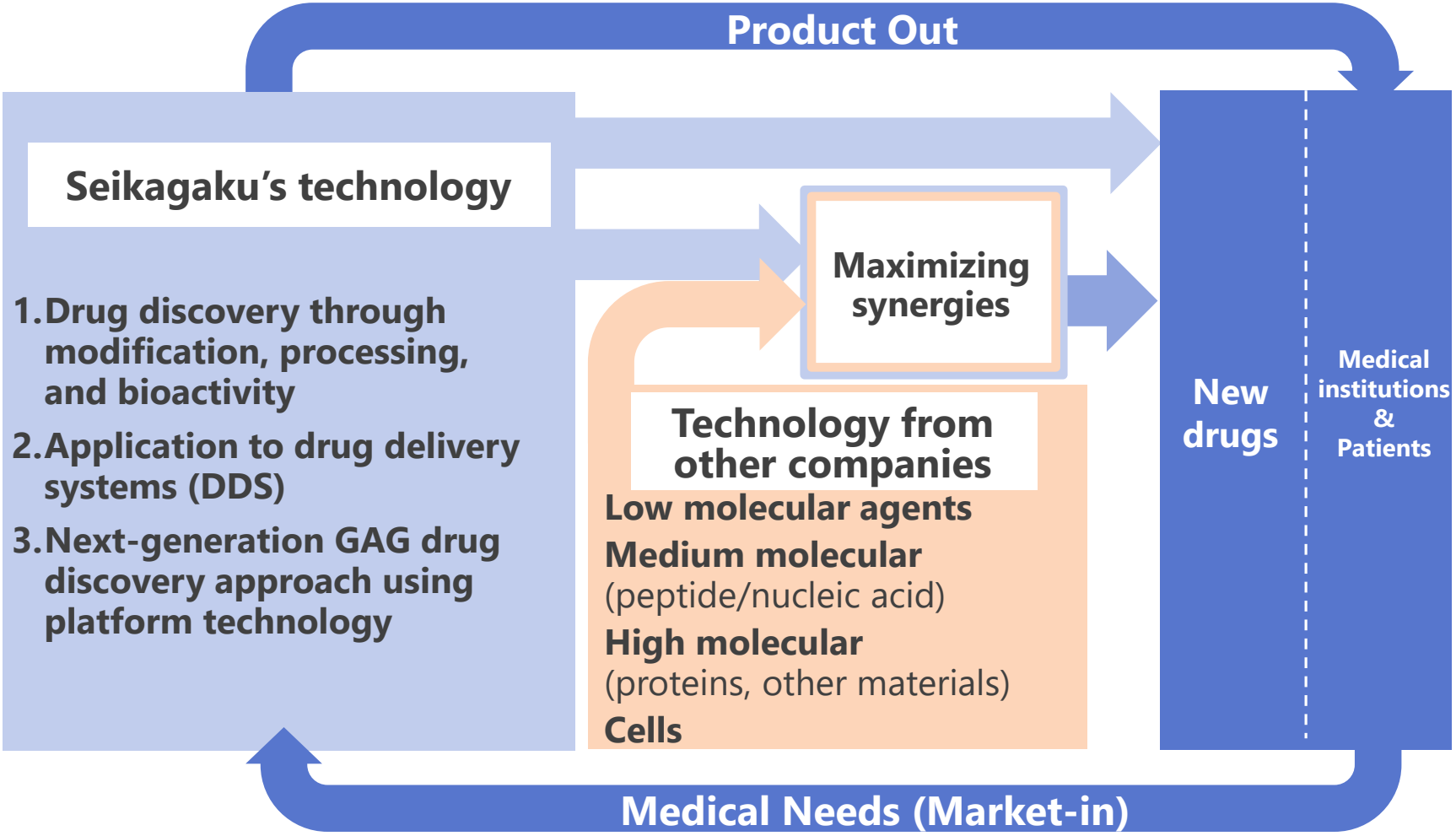
3. Next-generation GAG drug discovery approach using platform technology

- Conversion from natural GAG **to fermented GAG**
- Expanding the field of sugar chain drug discovery
  Applying to glycobiology

SI-613
SI-614

Accelerating Innovative Drug Discovery Using The Open Innovation Strategy

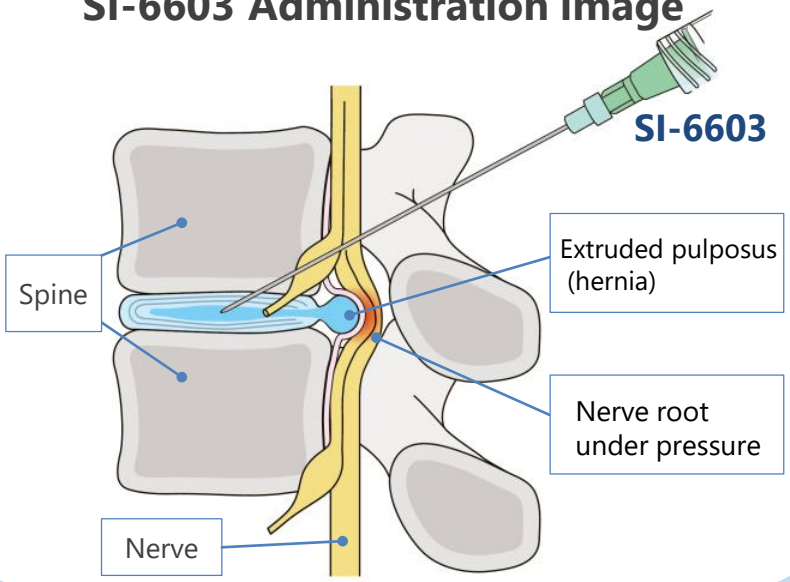
Speeding up and augmenting the number of projects through a drug discovery approach using Open Innovation



SI-6603 (Treatment for Lumbar Disc Herniation)

Single injection expected to relieve the pain of lumber disc herniation by decreasing intradiscal pressure and then reducing the pressure on nerve root

SI-6603 Administration image



Expected Features

- ▶Relieving symptoms by decreasing intradiscal pressure and reducing the pressure on the nerve root by single injection
- ▶It can be administered without general anesthesia, and the administration can be less invasive for the patient compared to surgical technique because of direct intradiscal injection

<SI-6603 summary>

Dev. Code : SI-6603 Generic name : Condoliase

Indication : Lumbar disc herniation

Method of use : Injection into lumbar disc (under X-ray observation)

Estimated U.S. patients : New patients with lumbar disc herniation: 3 to 5 million per year

(Seikagaku estimates)

Result for SI-6603 Phase III Clinical Study in the U.S.

Significant improvement in the primary endpoint was demonstrated in Phase III study of Japan but Phase III study in the U.S. did not meet its primary endpoint of pain improvement

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.

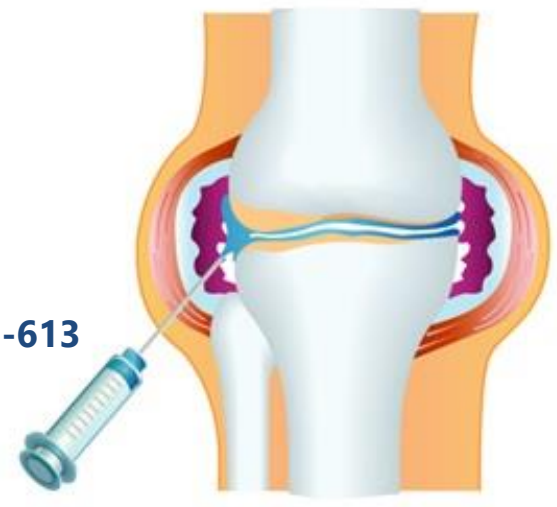
② There is possibility that some factors such as complications biased assessment of leg pain

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

SI-613 (Treatment of Osteoarthritis/Enthesopathy)

Aiming at prompt and sustained relief of the pain and inflammation associated with osteoarthritis or Enthesopathy

SI-613 Administration image



Expected Features

▶Hyaluronic acid and diclofenac (an anti-inflammatory agent) are chemically bound by the drug deriverly system
SI-613 is designed for sustained release * of diclofenac
Prompt and sustained relief of pain and inflammation

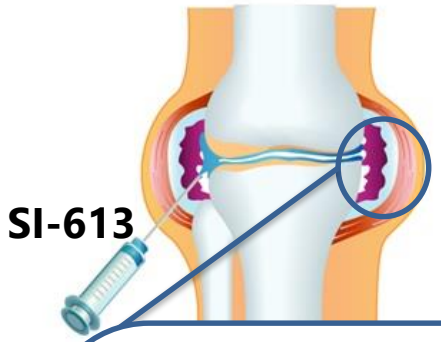
▶Since SI-613 is directly injected into the affected area as an injectable treatment, systemic exposure to diclofenac is low
Low risk of systemic side effects

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

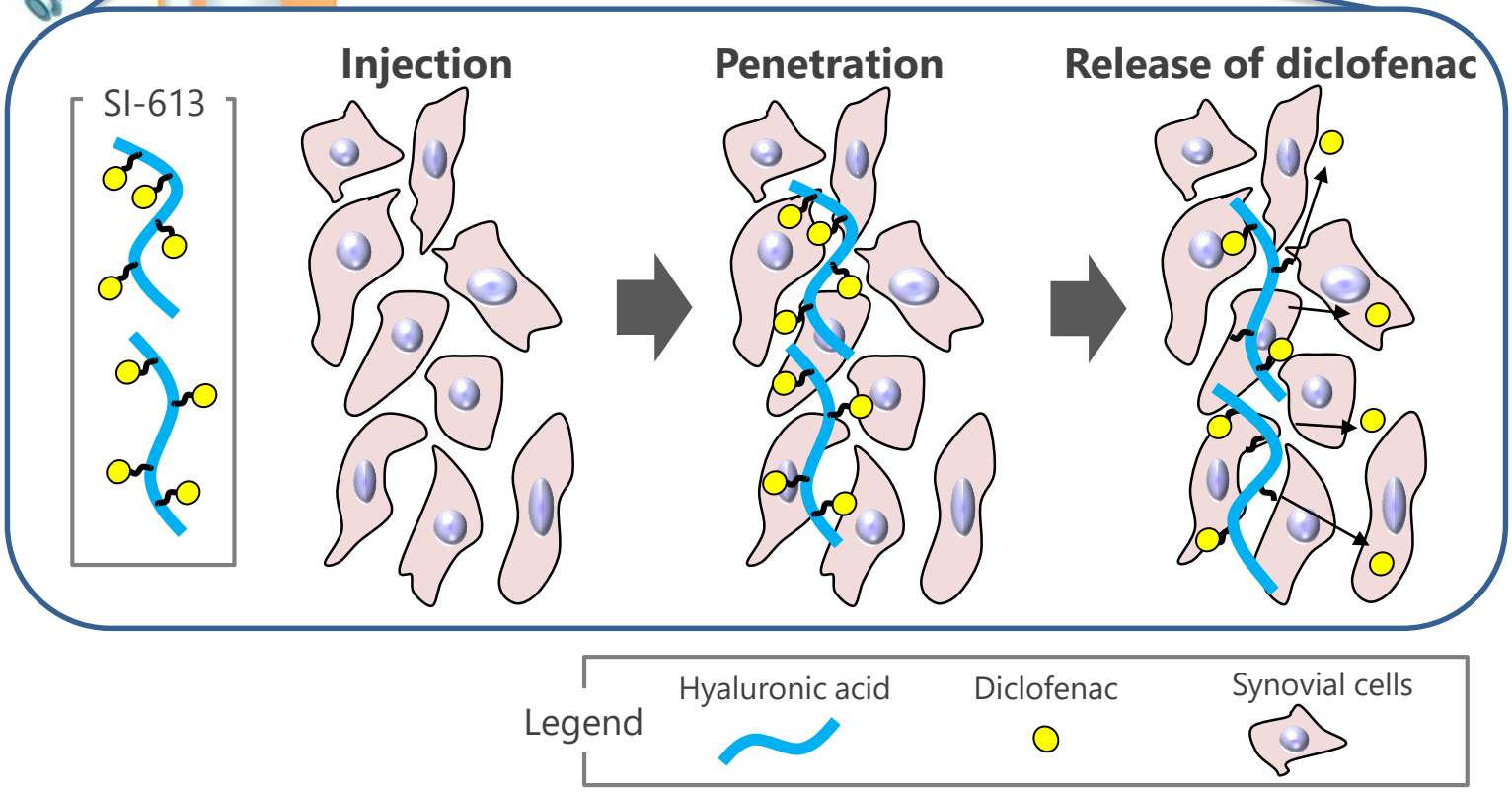
<SI-613 summary>
Dev. code : SI-613 Generic name : Hyaluronic Acid-Diclofenac Conjugates
Indication : Osteoarthritis/Enthesopathy
Method of use : Injection into joint cavity

Estimated patients : 7.8 million (Seikagaku estimates)

Sustained Release of Diclofenac in SI-613

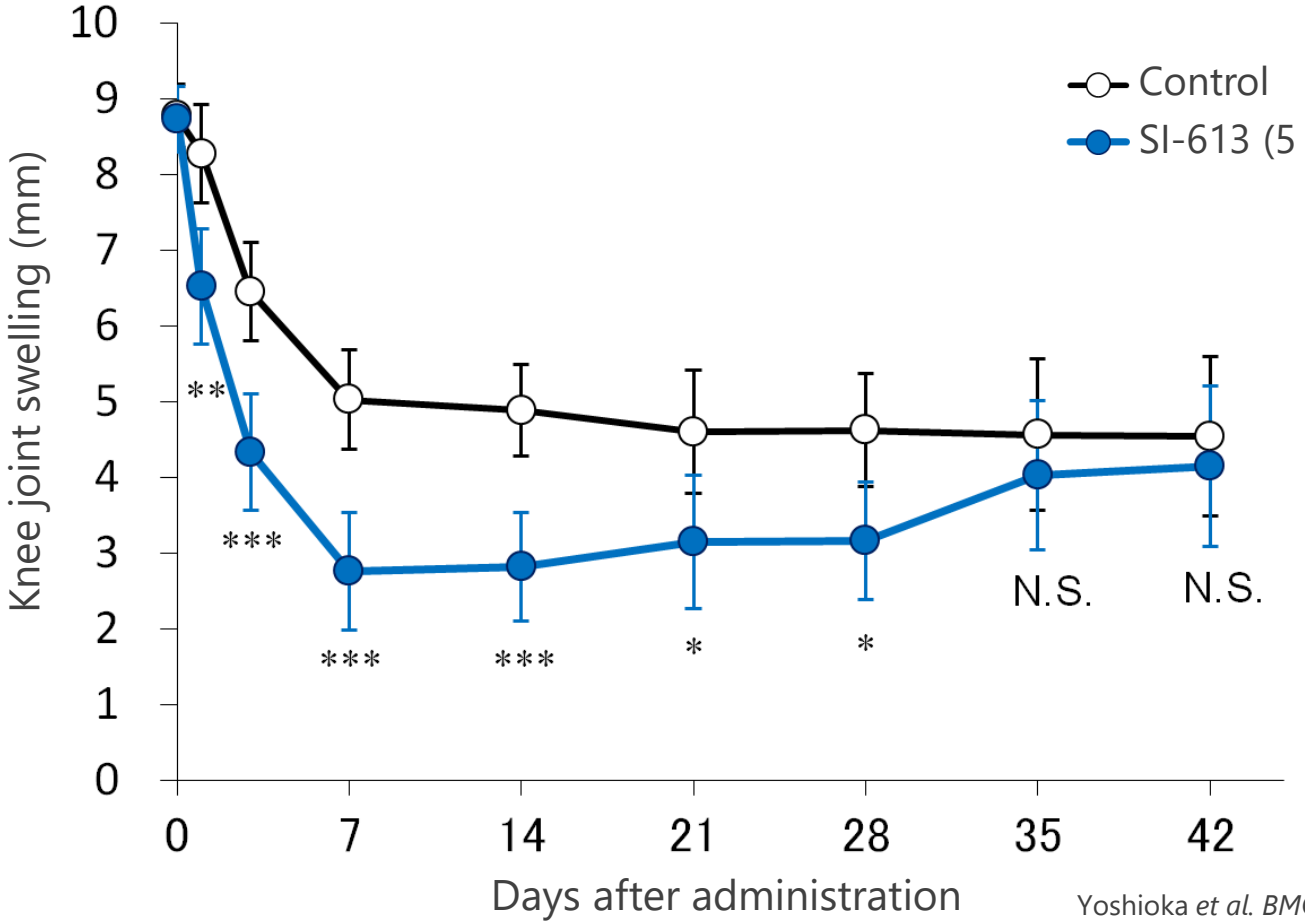


SI-613 (substance name: hyaluronic acid-diclofenac conjugate) is thought to penetrate the synovial membrane (connective tissue within the articular capsule) and gradually release diclofenac



Results of Non-clinical Study for SI-613

Results of non-clinical study : Anti-inflammatory effect of SI-613 on antigen-induced arthritis in rabbits



Mean±S.E. (n=20)
*** P<0.001, ** P<0.01, * P<0.05
N.S.(not significant) :
Student's *t*-test with
Holm's correction (vs control)

Yoshioka *et al. BMC Musculoskeletal Disorders* (2018) 19:157
https://doi.org/10.1186/s12891-018-2077-8

SI-613 (Treatment of Osteoarthritis/Enthesopathy)

Academic conference presentation of the results of a phase III study in Japan of SI-613 in patients with knee osteoarthritis

Outline of Conference Presentation

The results of a phase III study in Japan of SI-613 in patients with knee osteoarthritis were presented at the 93rd Annual Meeting of the Japanese Orthopaedic Association, an online meeting held from June 11 to August 31, 2020.

Abstract Number: 3-12-15
The phase III study of Diclofenac etalhyaluronate (ONO-5704/SI-613) in osteoarthritis of the knee

Conducted as a randomized, double-blind, placebo-controlled, parallel-group comparative study in 440 patients with knee osteoarthritis to evaluate efficacy and safety

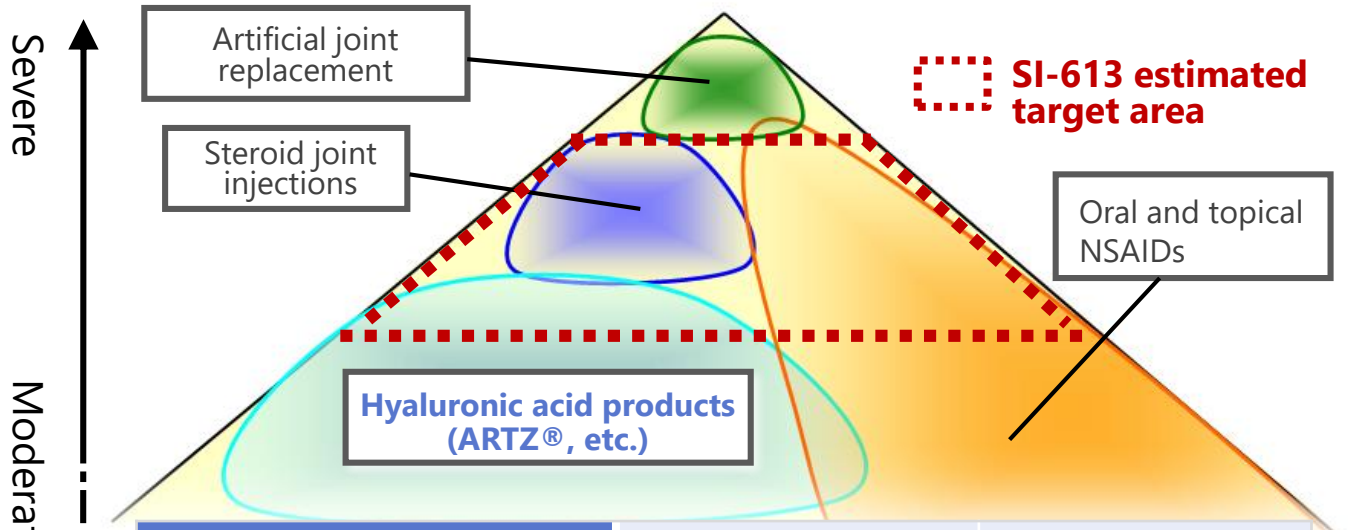
Primary endpoint: WOMAC pain score
Statistically significant difference found versus the placebo group in difference in mean change in WOMAC score from baseline to 12 weeks after initial administration

Main Secondary endpoints: WOMAC stiffness score and physical function score
Statistically significant difference found versus the placebo group in difference in mean change in WOMAC scores from baseline to 12 weeks after initial administration

Safety evaluation:
No difference in frequency of adverse events and no clinically evident problems found

SI-613 Estimated Target Patients

Quickly fostering approval and launching as a new core product

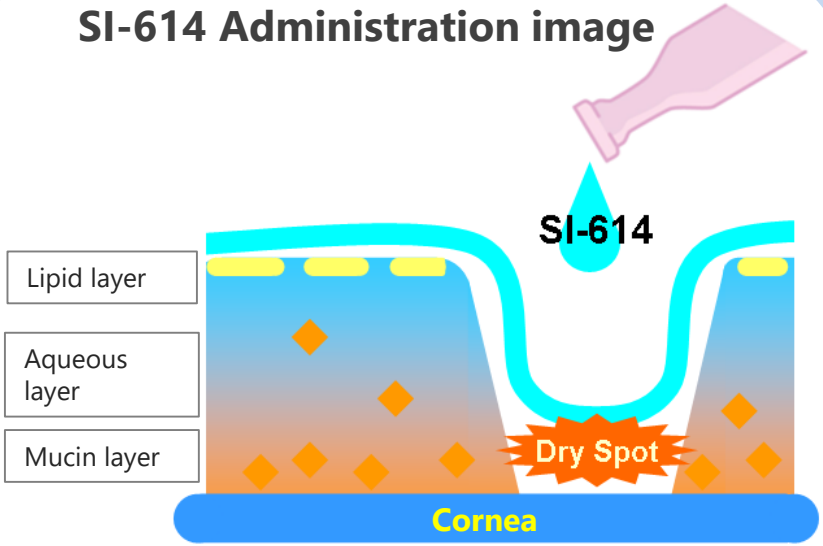


Target market size in Japan ＊Including applications outside the knee		
	Oral NSAIDs	¥ 83 billion
	Topical NSAIDs	¥144 billion
	HA injections	¥41 billion
	Steroid injections	¥11 billion

*Numbers in this slide are estimated by Seikagaku, as of March 31, 2019

SI-614 (Treatment of Dry Eye)

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



Development status

▶ **U.S. : P II/III**

- January 2015: Phase II/III clinical study completed
- Plan to conduct a PIII study after a sales partner has been decided

infection

Promising features

▶SI-614 Improves symptoms of dry eye by protecting the ocular surface and promoting corneal epithelial wound healing

▶Dry Eye is a multifactorial disease, and Seikagaku aims to provide a treatment option based on a new mechanism unavailable from existing products

<SI-614 summary>

Dev. Code : SI-614 Generic name : Modified Hyaluronate

Product name : Dry eye Formulation : Ophthalmic solution

Estimated U.S. patients : 4.9 million (Seikagaku estimates)

Clinical Study Information

Development code/ Indication	Develop-ment Location	Clinical Study Title (Study ID)	Target Enroll-ment	Estimated Period	Primary End Point (Primary Follow-up period)
SI-6603 Lumbar Disk Herniation	U.S.	Phase III additional study (NCT03607838)	320	May. 2018 – Nov. 2022	Leg pain (13 weeks)
SI-613 Osteoarthritis	Japan	Phase III Knee confirmatory study (JapicCTI-173537)	440	Feb. 2017 – Jan. 2019	WOMAC(Knee pain) (12 weeks)
		Phase III study for four sites (JapicCTI-173678)	280	Aug. 2017 – Jun. 2019	Daily pain diary (12 weeks)
		Long-term administration study(JapicCTI-183855)	160	Feb. 2018 – Sep. 2019	Safety (52 weeks)
SI-613-ETP Enthesopathy	Japan	Late-stage Phase II clinical study (JapicCTI-173758)	240	Oct. 2017 – Oct. 2018	Pain in motion (4 weeks)
SI-613 Knee Osteoarthritis	U.S.	Phase II clinical study (NCT03209362)	80	Oct. 2017 – Nov. 2018	WOMAC(Knee pain) (12 weeks)
SI-614 Dry eye	U.S.	Phase II / III clinical study (NCT02205840)	240	Jul. 2014 – Nov. 2014	Corneal staining score, Symptom score (28 days)
SI-722 Interstitial cystitis and bladder pain syndrome	U.S.	Phase I / II clinical study (NCT04208087)	32	Dec. 2019 – Jun. 2020	Maximum observed plasma concentration
SI-449 Adhesion Barrier	Japan	Pivotal study (JapicCTI-205343)	130	Jun. 2020 – Dec. 2022	efficacy

Note: The table shows data registered (or planned to be registered) on clinical trial information websites. The information is updated from time to time. Refer to the websites for details and the latest information. (The websites can be accessed from the trial ID links.)
- Japan Pharmaceutical Information Center(JAPIC) http://www.clinicaltrials.jp/user/cteSearch_e.jsp
- University hospital Medical Information Network (UMIN) Center http://www.umin.ac.jp/ctr/index.htm
- ClinicalTrials.gov https://clinicaltrials.gov/ct2/search

Note: Actual enrollments or trial periods may differ from targets and plans due to various factors.

Contract Status by R&D Theme

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

Development Code Indication	Develop-ment Location	Sales Partner	Total Amount of Milestone Royalties (of which, in upfront payment)
SI-6603 Lumbar Disk Herniation	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. ¥12.0 billion (¥2.0 billion)
	U.S.	Searching	—
	China	Eisai Co., Ltd.	—
	Korea	Eisai Co., Ltd.	—
SI-613-ETP Enthesopathy	Japan	Ono Pharmaceutical Co., Ltd.	*included in the above
SI-614 Dry eye	U.S.	Searching	—
SI-722 Interstitial cystitis	U.S.	—	—
SI-449 Adhesion Barrier	Japan	—	—

Numerical targets

	FY2018 results	FY2021 targets
Net sales	¥28.3 billion	¥28.3 billion
Ordinary income	¥2.8 billion	¥4.5 billion
SKK EBITDA *	¥4.6 billion	¥5.0 billion
Overseas sales ratio	42.2%	50.0%

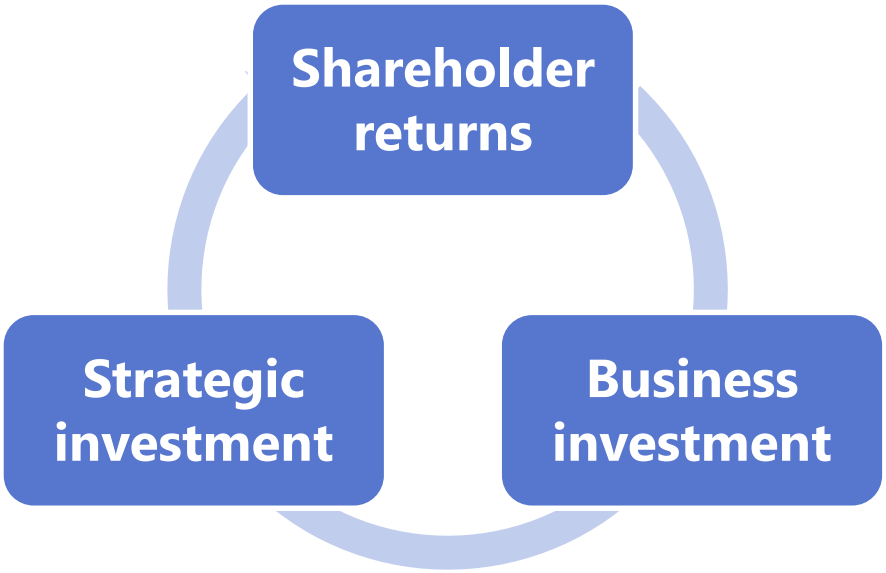
≪ Assumptions≫

- Expansion of overseas sales in the LAL business makes up for the effects of the NHI drug price revisions in Japan
- Depreciation declines as a result of impairment loss
- R&D expenses are 25–30% of sales
- Various royalty income is included as non-operating income
- Exchange rate: ¥105 to the U.S. dollar

＊SKK EBITDA：A profit indicator that adds depreciation and royalty income to operating income

Basic policy on profit distributions

Investing for sustainable profit growth and raising corporate value, implement business performance-linked dividends



Shareholder returns
- Aiming for a 50% dividend payout after considering business profits etc.
- Examining the purchase of company treasury stock when appropriate

Business investment

Investing efficiently in R&D and production facilities etc. for creating new value

Strategic investment

Carrying out initiatives for strategic investments with prospects for future growth and synergy effects

*** Dividend plan: FY2019-¥26, FY2020 & 2021-based on dividend policy described here**

Seikagaku's vision

Our vision	A company that is valued by the world through its innovative drug discovery
Core values (motto)	Creativity, Fairness, Dreams and Passion
Creed	We create safe and useful products for human well-being with basic research based on glycoscience.
Guidelines for Our Activities	● We create a corporate environment of mutual trust and communication using individual abilities. ● We create innovative and useful products through in-depth cooperation between industrial and academic circles. ● We assure the highest quality and safety of our products. ● We enhance interaction with society by establishing genuine trust. Through these efforts, Seikagaku will strive to become a sound and socially responsible company that protects the natural environment and improves quality of life.
Mission statement	"Glycoscience for human well-being"
Corporate slogan of the new mid-term management plan	”Innovative Thinking” Creating value based on innovative thinking

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 State-of-the-art technology related to GAG

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

3 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

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

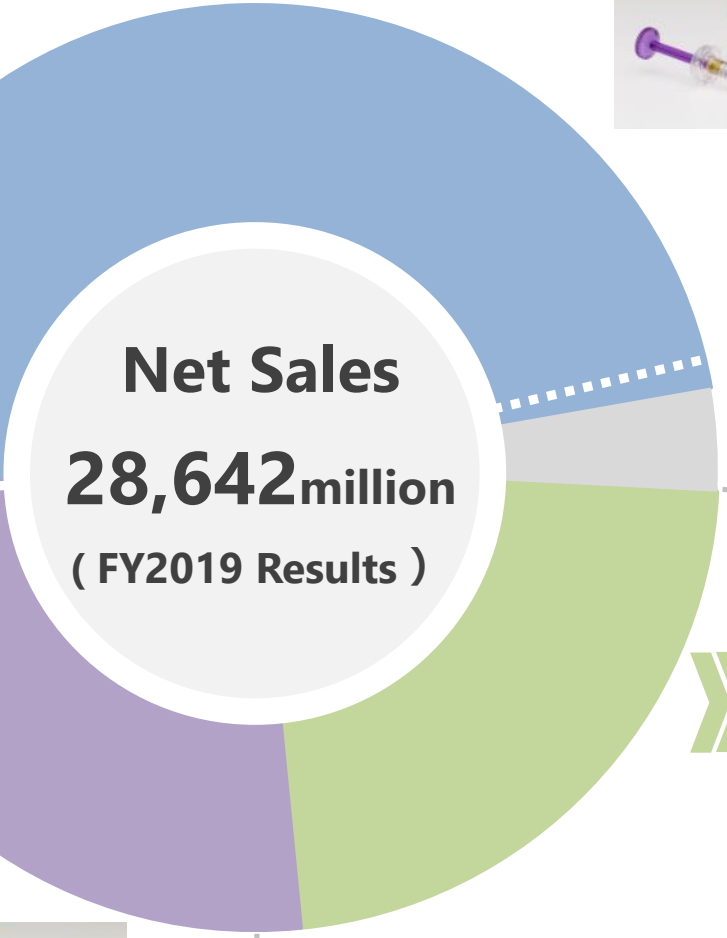
Our Business Segment

Pharmaceutical Business 77.4%

Domestic Pharmaceuticals ➡47.8%

Joint Function Improving Agents

Overseas Pharmaceuticals ➡26.1%



Ophthalmic Surgical Aids

Bulk Products

Bulk Products ➡3.6%

LAL Business 22.6%

Endotoxin-detecting reagents
(used mainly for quality control of pharmaceuticals and medical devices)

Main Hyaluronic Acid (HA) Products

ARTZ® Joint function improving agent 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® Intra-articular single-injection viscosupplement for the treatment of knee osteoarthritis

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

■ Cautionary Notes

This material contains forward-looking statements regarding future management strategies or performance forecasts. These descriptions 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 descriptions due to various factors.Information about pharmaceutical products or medical devices (including products currently in development) contained in this material is not intended to constitute an advertisement or medical advice.

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