

Financial Results
for the 3rd Quarter of Fiscal Year 2019
(April 1, 2019 – December 31, 2019)



SEIKAGAKU CORPORATION

(TSE:4548)

Contents

■ 3Q Financial Results	P3	■ Research and Development	P9
● Net Sales	P4-6	● SI-613 (Osteoarthritis/Enthesopathy)	P10
● Income	P7	● SI-6603 (Lumbar disc herniation)	P12
● Trend in R&D Expenses	P8	● SI-614 (Dry Eye)	P14
		● SI-722 (Interstitial cystitis and bladder pain syndrome)	P15
		● SI-449 (Adhesion Barrier)	P16
		■ Basic Policy on Profit Distribution	P18
		■ Appendix	P19

< 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 3Q of FY2019

(Millions of Yen)	3Q FY2019 Results	Year-on-Year		(Reference) FY2019 Revised Forecasts	
		Change	% of Change	FY 2019 Forecasts	Degree of Progress
Net Sales	23,240	+1,653	+7.7%	28,600	81.3%
Operating Income	3,265	+1,914	+141.6%	1,350	241.9%
Ordinary Income	3,868	+915	+31.0%	3,750	103.2%
Extraordinary Income and Loss	-12,441	-12,441	—	-13,550	—
Net Income and Loss	-9,781	-12,035	—	-11,000	—
R&D Expenses (Ratio to net sales)	4,457 (19.2%)	-534 (-3.9pt)	-10.7%	7,000 (24.5%)	63.7%
Average Exchange Rate (1US\$)	¥108.67	¥-2.48		2Q forecast ¥105.00	
		3Q FY2019 Results	3Q FY2018 Results	(Reference) FY2019 Forecasts	
Net Income and Loss per Share		¥-173.40	¥39.91	¥-194.99	

Net sales by Business Segment (3Q of FY2019)

(Millions of Yen)	3Q FY2019 Results	Year-on-Year	% of Change
Net Sales	23,240	+1,653	+7.7%
Pharmaceuticals	18,348	+1,635	+9.8%
Domestic Pharmaceuticals	11,470	+532	+4.9%
Overseas Pharmaceuticals	6,046	+1,136	+23.1%
Bulk Products	831	-33	-3.9%
LAL Business	4,892	+18	+0.4%
(Overseas Sales)	10,143	+1,175	+13.1%

* Foreign exchange impact on overall net sales : approx. -160million yen

Domestic Pharmaceuticals

▶ **ARTZ** (Joint-function improving agent)

- Market: -2.3%
- ARTZ deliveries to medical institutions: -1.7%
Market share of 60.1% (+0.4 pt) due to measures to promote switching from competing products
- Seikagaku sales up, reflecting a low level of shipments in FY2018 due to a sales partner inventory adjustment

▶ **OPEGAN series** (Ophthalmic viscoelastic devices)

- Market: +13.1%
- OPEGAN series deliveries to medical institutions: +18.9%
SHELLGAN and the OPEGAN series Increase as a whole
- Large increase in Seikagaku sales as well

▶ **MucoUp**

(Submucosal injection agent for endoscopic surgery)

- Seikagaku sales decline due to the impact of the introduction of competing products on the market

▶ **HERNICORE**

(Treatment for lumbar disc herniation)

- Deliveries to medical institutions and Seikagaku sales up
- Active engagement in information provision activities directed at medical institutions

Net sales by Business Segment (3Q of FY2019)

(Millions of Yen)	3Q FY2019 Results	Year-on-Year	% of Change
Net Sales	23,240	+1,653	+7.7%
Pharmaceuticals	18,348	+1,635	+9.8%
Domestic Pharmaceuticals	11,470	+532	+4.9%
Overseas Pharmaceuticals	6,046	+1,136	+23.1%
Bulk Products	831	-33	-3.9%
LAL Business	4,892	+18	+0.4%
(Overseas Sales)	10,143	+1,175	+13.1%

* Foreign exchange impact on overall net sales : approx. -160million yen

Overseas Pharmaceuticals

*Foreign exchange impact on Overseas Pharmaceuticals: approx. -140 million yen

U.S.

► **Gel-One** (Single injection)

- 35% increase in local sales due to sales expansion measures by the sales partner
- Preferential reimbursement status obtained from multiple insurance companies
- Large increase in Seikagaku sales accompanying strong local sales

► **SUPARTZ FX** (Multiple injection)

- Local sales and Seikagaku sales down amid continuing trend toward preference for products that require a low number of injections

China, Other Regions

► **China**

- Local sales volume and Seikagaku sales down, reflecting a distribution inventory adjustment by the sales partner

► **Italy**

- Favorable sales since the launch of HyLink in March 2019

Net sales by Business Segment (3Q of FY2019)

(Millions of Yen)	3Q FY2019 Results	Year-on-Year	% of Change
Net Sales	23,240	+1,653	+7.7%
Pharmaceuticals	18,348	+1,635	+9.8%
Domestic Pharmaceuticals	11,470	+532	+4.9%
Overseas Pharmaceuticals	6,046	+1,136	+23.1%
Bulk Products	831	-33	-3.9%
LAL Business	4,892	+18	+0.4 %
(Overseas Sales)	10,143	+1,175	+13.1%

* Foreign exchange impact on overall net sales : approx. -160million yen

Bulk Products

At prior-year level as hyaluronic acid increased, but chondroitin sulfate declined

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

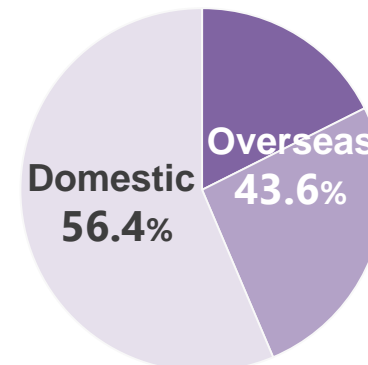
LAL Business

*Foreign exchange impact on LAL Business: approx. -20million yen

At prior-year level, with strong overseas sales compensating for a domestic decline

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

Overseas Sales Ratio



Year-on-Year
+2.1pt

Income for 3Q of FY2019 (Year-on-Year)

(Millions of Yen)	3Q FY2019 Results	Year-on-Year	% of Change
Net Sales	23,240	+1,653	+7.7%
Cost of Sales (Cost of sales ratio)	10,059 (43.3%)	+89 (-2.9pt)	+0.9%
SGA Expenses	9,914	-349	-3.4%
R&D Expenses (to Net sales ratio)	4,457 (19.2%)	-534 (-3.9pt)	-10.7%
Operating Income (to Net sales ratio)	3,265 (14.1%)	+1,914 (+7.8pt)	+141.6%
Ordinary Income	3,868	+915	+31.0%
Extraordinary Income and Loss	-12,441	-12,441	—
Net Income and Loss	-9,781	-12,035	—
Depreciation	1,611	-557	-25.7%

Operating Income

Cost of Sales Ratio (-2.9pt) :

- Decrease in depreciation in connection with impairment loss* on property, plant and equipment related to the pharmaceuticals business
- Impact of higher production of Gel-One and other factors

SGA Expenses (-349) :

- Drop in R&D expenses due to completion of clinical studies in Japan for SI-613, a treatment for osteoarthritis (-534)

Net Income and Loss

Non-operating Income/Expenses (-999) :

- Decrease in gain on sales of investment securities (-517)
- No royalty income recorded (-508)

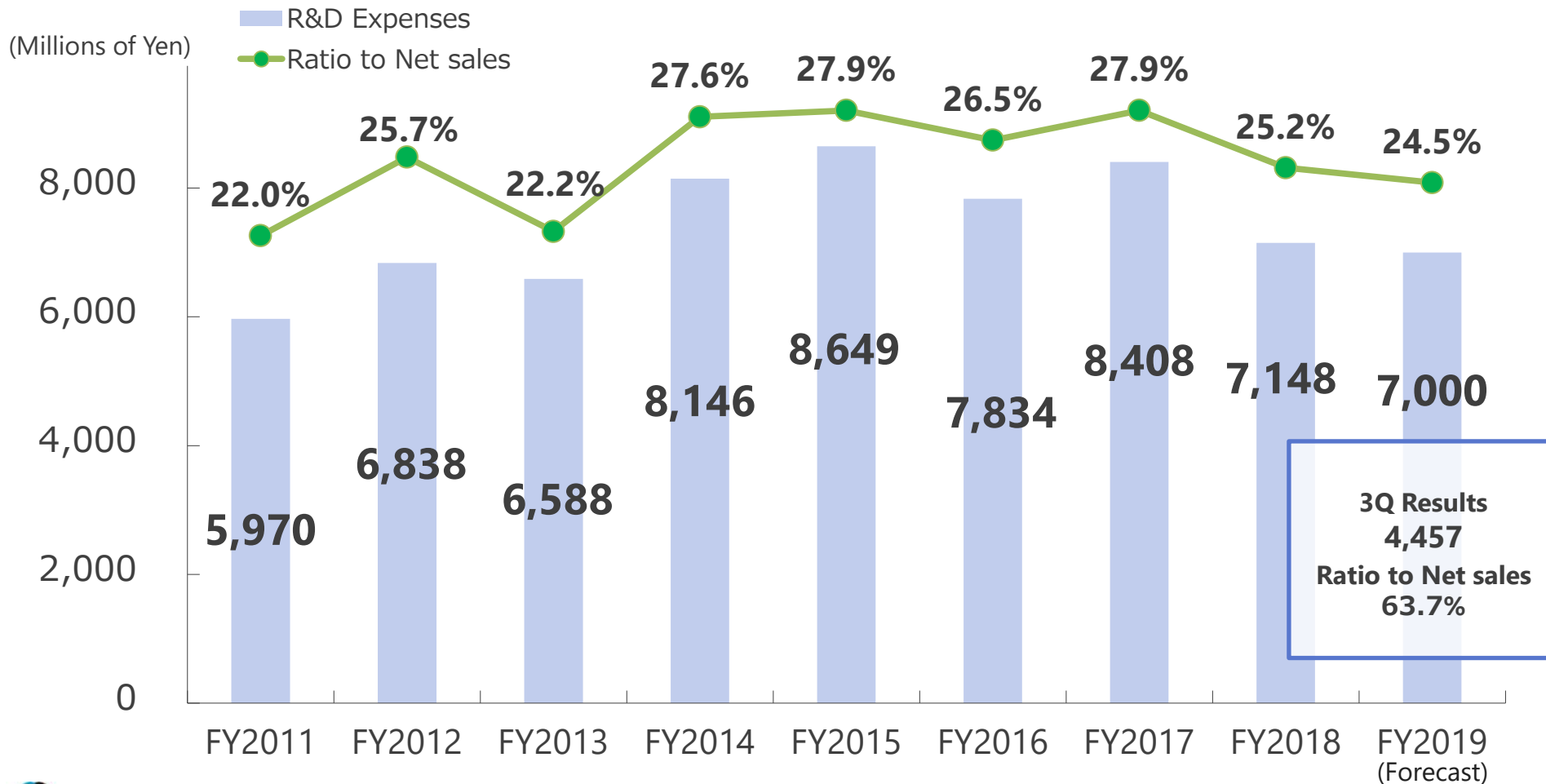
Extraordinary Income and loss (-12,441) :

- Recording of impairment loss* (-12,441)

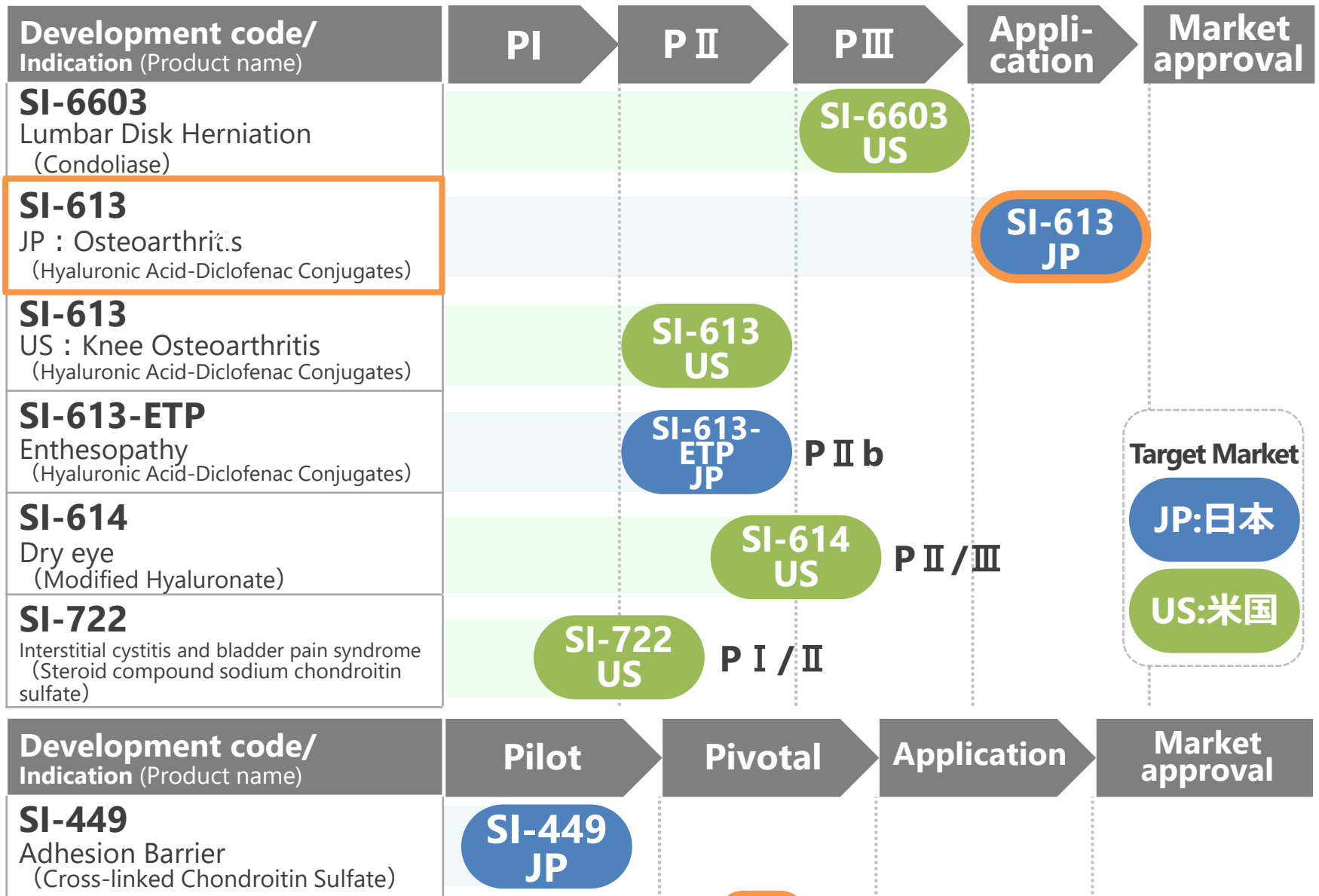
*Recognition of an impairment loss on property, plant and equipment related to the pharmaceuticals business as announced in Seikagaku Announces the Recognition of an Extraordinary Loss (Impairment Loss), released on November 8, 2019


Trend in R&D Expenses

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



Pipeline List (Research and Development themes)

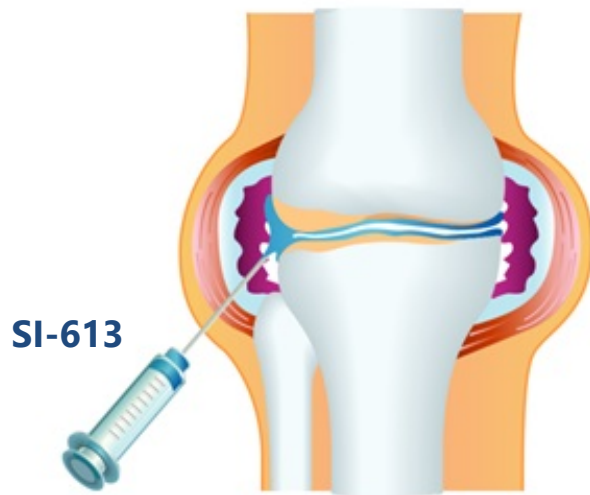


 : Changes from 2nd Quarter of Fiscal Year 2019

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 delivery 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)

SI-613 (Treatment of Osteoarthritis/Enthesopathy)

Submitted a new drug application (“NDA”) for manufacturing and marketing in Japan, for the treatment of osteoarthritis
Aiming to will work to obtain an approval of the Product as soon as possible

SI-613 (osteoarthritis) Japan

▶ **Submitted a new drug application (“NDA”) for manufacturing and marketing 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

SI-613-ETP (enthesopathy) Japan

▶ Analysis of Phase IIb clinical study results is complete
Next action is under consideration with Ono Pharmaceutical

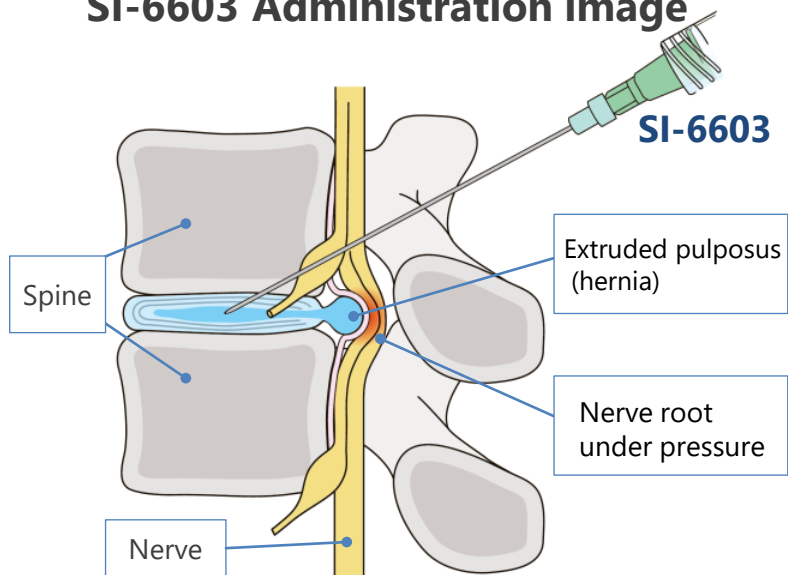
SI-613 (osteoarthritis of the knee) U.S.

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

SI-6603 (Treatment for Lumbar Disc Herniation)

Single injection expected to relieve the pain of lumbar 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)

SI-6603 (Treatment for Lumbar Disc Herniation)

**Pushing higher probability of success in additional study
Extending the study period and promoting the enrollment of subjects**

Development status

▶ **Additional Phase III study in the U.S.**

Initiated February 2018.

Extending enrollment by two years, aiming for November 2022 completion

Factors behind extension

- Strict standards for enrollment of subjects (imaging diagnostics, absence of opioid use, etc.)
- Time overrun in starting treatment facilities

Measures to promote enrollment

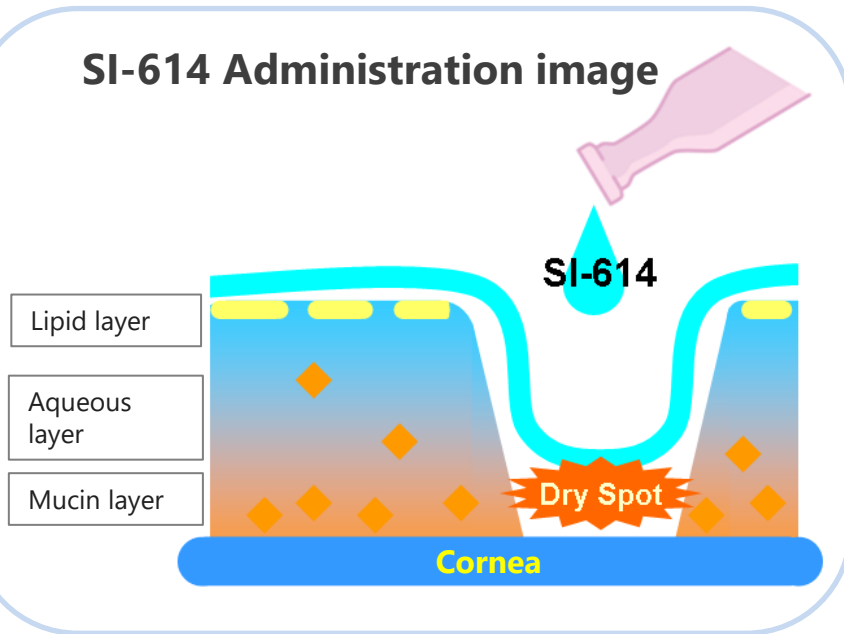
- Advertising suited to treatment facility requirements
Advertising online (Google and Facebook) and TV, radio, newspapers
- Strengthen coordination with medical institutions and increase patient introductions
- Link-up with support vendors specializing in facility selection to increase number of facilities

※Consider expansion into markets other than Japan and the U.S.
once prospects for a U.S. NDA are in sight

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

SI-614 Administration image



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

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

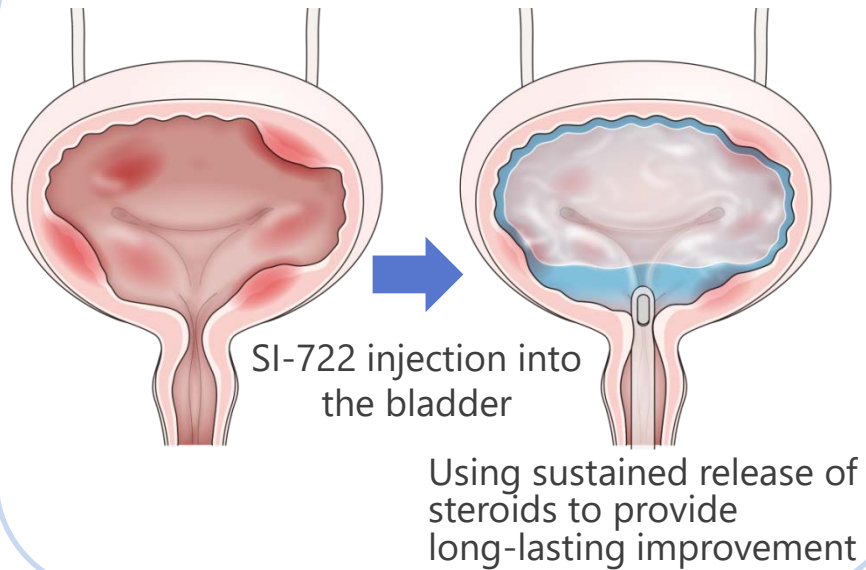
Formulation : Ophthalmic solution

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

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

**U.S. Phase I/II clinical study starting
Aiming to step up to Phase IIa during
the mid-term management plan period***

SI-722 Administration image



Development status

▶ U.S. Phase I/II

- **Starting November 2019**

- Study completion expected during FY2020

* Phase I completed in June 2019

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
- ▶ Improving patient quality of life

<SI-722 summary>

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

Indication : Interstitial cystitis and bladder pain syndrome

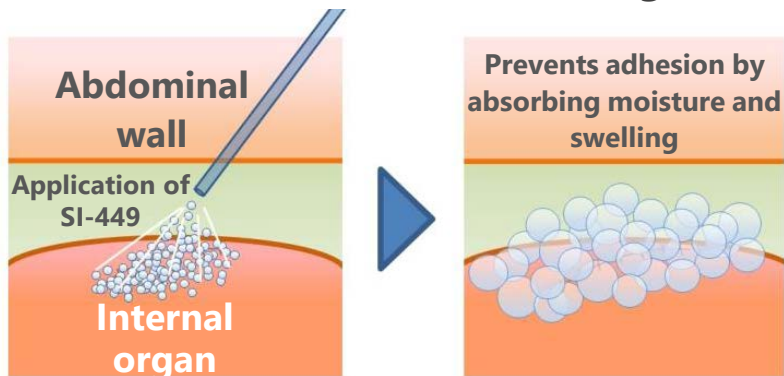
Method of use : Injection into the bladder

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

SI-449 (Adhesion Barrier / Medical Device)

**Pilot study to completion during FY2019
Aiming to start pivotal study during
the mid-term management plan period***

SI-449 Administration image



Development status

▶ Japan pilot study

- Starting May 2018
- Enrollment completed, follow-up observation ongoing
- **Aiming to start pivotal study during FY2020**

- ▶ 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)

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-449 Adhesion Barrier	Japan	Pilot study (UMIN000033294)	20	Jul. 2018 – Nov. 2019	Safety, Manageability (–)

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.

Basic Policy on Profit Distribution

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

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

	FY2014	FY2015	FY2016	FY2017	FY2018	FY2019 (Forecast)
Net Income per share	¥64.27	¥45.39	¥31.55	¥69.30	¥39.76	¥-194.99
Annual Total Dividend	¥26.00	¥26.00	¥31.00 [※]	¥26.00	¥26.00	¥26.00
Dividend Payout Ratio	40.5%	57.3%	98.3%	37.5%	65.4%	—

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

* There is no change in forecast announced on November 8, 2019.

Appendix

Revised Forecasts in FY2019

(Millions of Yen)	FY2019 Revised Forecasts	Initial Forecasts		FY2018 Results		(Reference) Degree of 2Q Progress
		Change	% of Change	Change	% of Change	
Net Sales	28,600	+350	+1.2%	+215	+0.8%	54.4%
Operating Income	1,350	+950	+237.5%	+372	+38.1%	159.3%
Ordinary Income	3,750	+1,450	+63.0%	+890	+31.2%	65.9%
Extraordinary Income and loss	-13,550	-13,900	—	-13,550	—	—
Net Income and Loss	-11,000	-13,000	—	-13,244	—	—
R&D Expenses (Ratio to net sales)	7,000 (24.5%)	+200 (+0.4pt)	+2.9%	-148 (-0.7pt)	-2.1%	43.0%
Average Exchange Rate (1US\$)	<small>2Q forecast</small> ¥105.00	—		—		

	FY2019 Revised Forecasts	FY2019 Initial Forecasts	FY2018 Results	Exchange Rate Sensitivity (Impact of a change of ¥1 against the US\$)	
Net Income per share	¥-194.99	¥35.46	¥39.76	Net sales (2Q only)	Approx. ¥50 million
Dividend per share	¥26.00	¥26.00	¥26.00	Operating income (2Q only)	Approx. ¥15 million
Dividend Payout ratio	—	73.3%	65.4%		

* There is no change in forecast announced on November 8, 2019.

Revised Net Sales in FY2019 (Comparison with the initial forecast)

(Millions of Yen)	FY2019 Revised Forecasts	Initial Forecasts	
		Change	% of Change
Net sales	28,600	+350	+1.2%
-Pharmaceuticals	22,050	+450	+2.1%
-LAL Business	6,550	-100	-1.5%
Operating Income (Ratio to net sales)	1,350 (4.7%)	+950 (+3.3pt)	+237.5%
Ordinary Income	3,750	+1,450	+63.0%
Extraordinary Income and Loss	-13,550	-13,900	-
Net Income and Loss	-11,000	-13,000	-
Cost of Sales ratio	44.1%	-3.0pt	
R&D Expenses (Ratio to net sales)	7,000 (24.5%)	+200 (+0.4pt)	+2.9%
Depreciation	1,750	-1,200	-40.7%

Net sales

Pharmaceutical business increases led by Gel-One in the U.S.

* Total foreign exchange impact on net sales: +¥290 million

Operating Income

Raised forecast for operating income to reflect small depreciation expense in second half as a result of impairment loss

Cost of sales ratio:

Improved due to lower depreciation as a result of impairment loss

SGA Expenses (approx. +100) :

Engaged in enrolling subjects U.S. clinical study for SI-6603

Net Income and Loss

Net income forecast lowered substantially due to impairment loss

Non-operating income:

Forecasting higher royalty income

Extraordinary loss:

Impairment loss on property, plant and equipment (including more in 2Q)

* There is no change in forecast announced on November 8, 2019.

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

ARTZ (Joint-function improving agent)

● 2Q FY2019 Results

- Slight increase against generally flat market as sales promotion
(growth rate : +0.4% / Market growth rate : +0.1% / Market share : 59.4% (+0.2pt))

▶ FY2019 Forecasts

- Maintaining volumes supported by sales promotion campaigns using reconstruction of evidence data
(growth rate : +0.2% / Market share : 60.0%)



OPEGAN (Ophthalmic viscoelastic devices) ※including SHELLGAN

● 2Q FY2019 Results

- SHELLGAN keeps up the overall good performance of OPEGAN series, whose share is also expanding

(growth rate : +11.5% / Market growth rate : +10.4% / Market share : 44.3% (+0.4pt))

▶ FY2019 Forecasts

- Raising our forecast from the initial one due to switching from competing products

(growth rate : +5.4% ⇒ +18.5% / Market share : 45.8% ⇒ 47.0%)



HERNICORE (Treatment for lumbar disc herniation)

● 2Q FY2019 Results

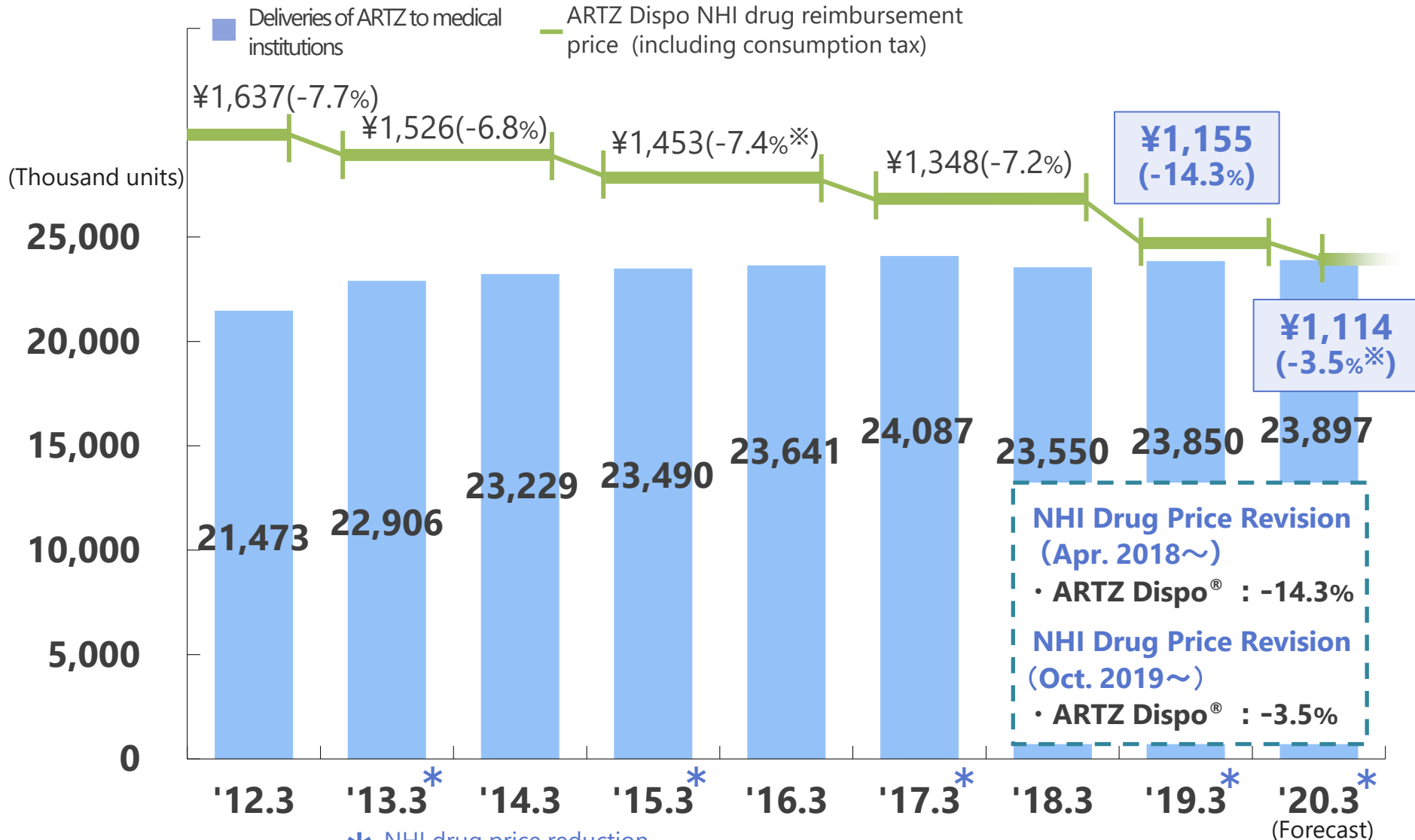
- Market penetration proceeding steadily as deliveries to medical institutions increase

▶ FY2019 Forecasts

- Seeking further market penetration through information provision activities to ensure appropriate use and safety.



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

* There is no change in forecast announced on November 8, 2019.

Trend in Deliveries of ARTZ / OPEGAN to Domestic Medical Institutions

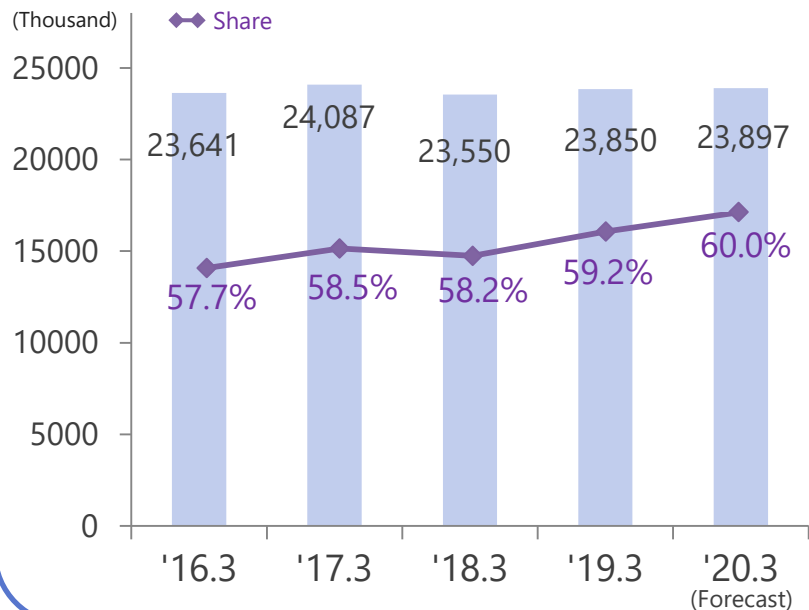
Joint-function improving agent

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



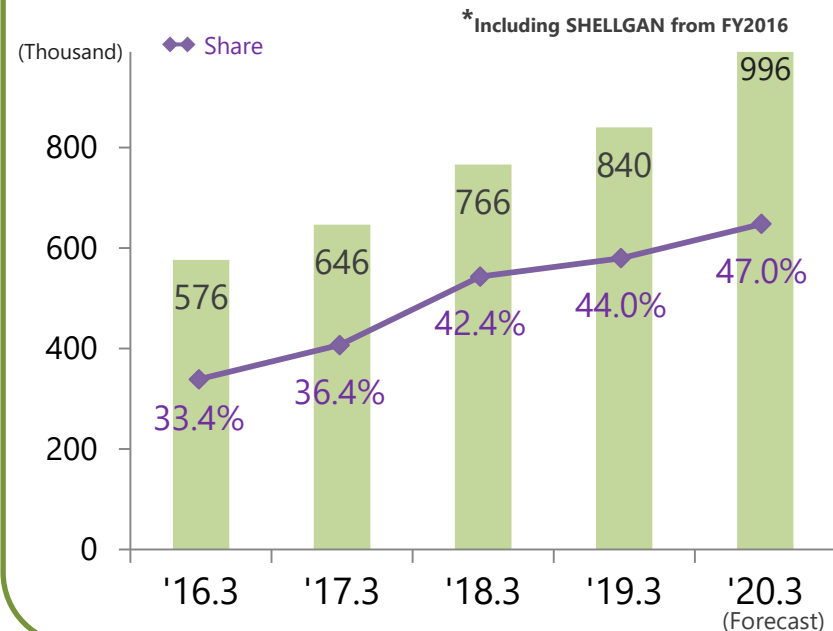
Ophthalmic viscoelastic devices

OPEGAN



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

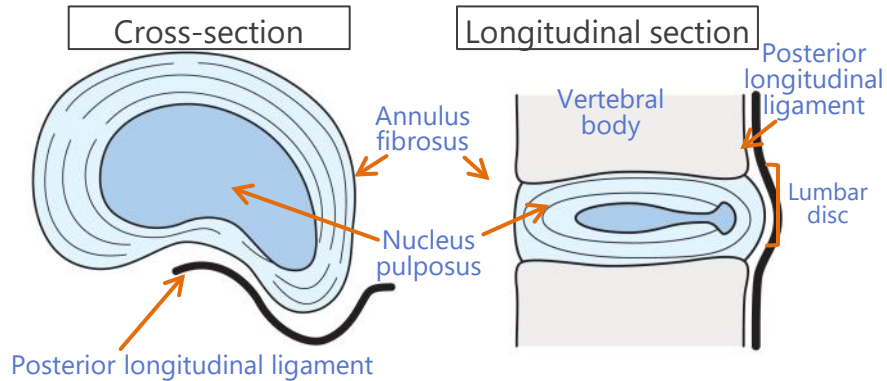
Trend in unit deliveries to medical institutions



Four types of lumbar disc herniation

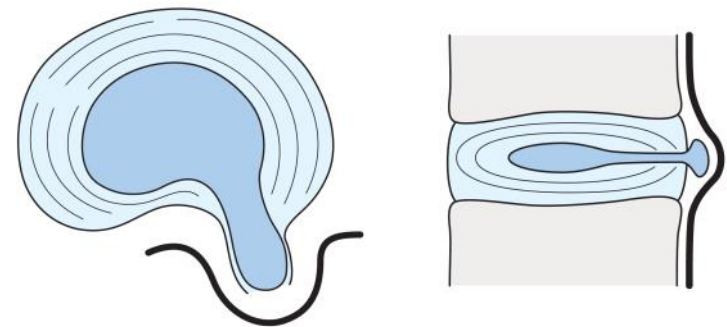
1. Protrusion

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



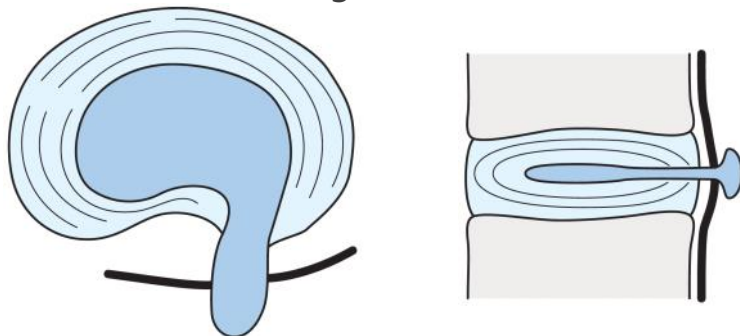
2. Subligamentous extrusion

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



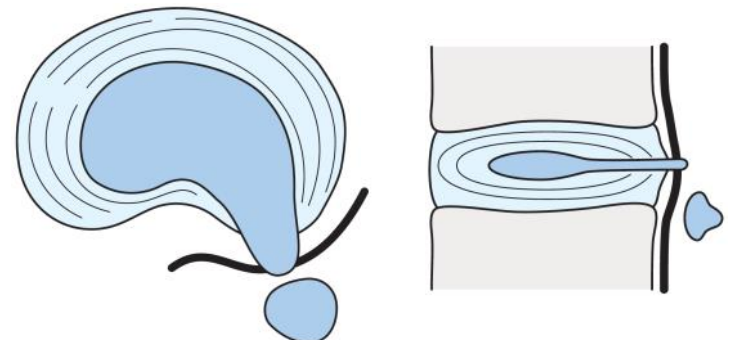
3. Transligamentous extrusion

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)



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

• 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

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
 ② Physicians 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
 ② Physicians 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 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.

Ophthalmic viscoelastic devices SHELLGAN

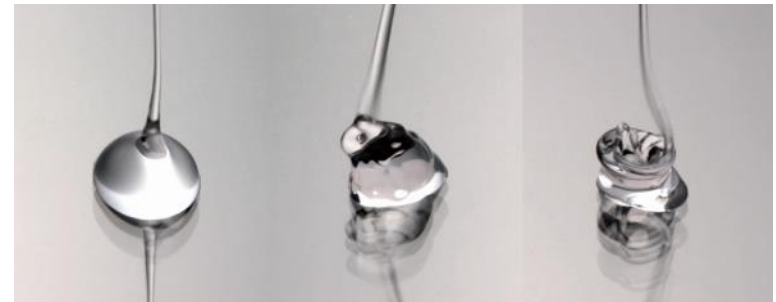


■ Product SHELLGAN Outline

- 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



OPEGAN OPEGAN HI SHELLGAN

The OPEGAN series viscoelasticity comparison

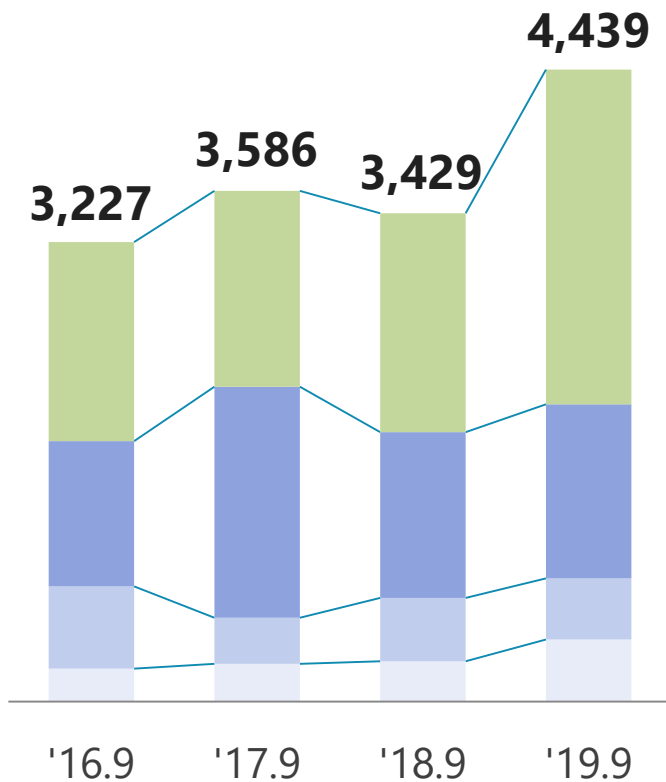
Overseas Pharmaceuticals (2Q FY2019 Results Year-on-Year / value basis)

Overseas Pharmaceuticals Sales trend

(Millions of Yen)

<Breakdown>

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



2Q FY2019 Results

+29.5%

Gel-One up considerably, SUPARTZ FX in the U.S. slightly increasing. ARTZ in China declines

U.S.

● Sales in the U.S.:

- Gel-One** : Increase due to acquiring preferred reimbursement status from multiple insurance companies and successful measures to switch from competing products
(+35% volume-based)
- SUPARTZ FX** : A downward effect from the continuing trend towards selection of products requiring fewer injections, including single- and three-injection
(-16% volume-based)
- ▶ Seikagaku exports :**
 Gel-One has a large increase with greater local sales volume; SUPARTZ FX up slightly owing to shipments being moved forward

China, Other Regions

● Local sales of ARTZ in China

Increasing due to successful sales expansion in cities and also surrounding areas
(+16% volume-based)

▶ Seikagaku exports :

ARTZ in China declines due to shipment timing and foreign exchange effects
 HyLink in Italy having an effect, leading to increase

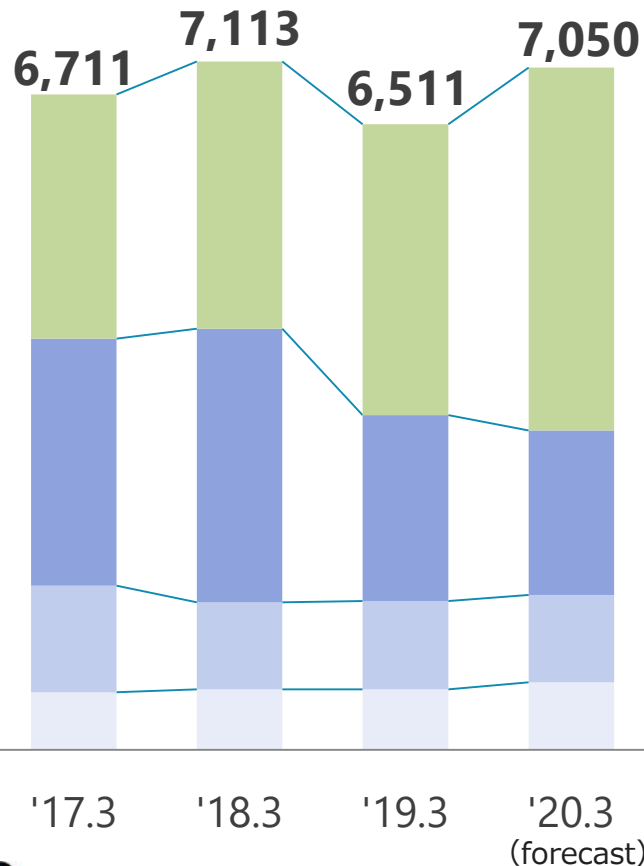
* There is no change in forecast announced on November 8, 2019.

Overseas Pharmaceuticals (FY2019 Forecast Year-on-Year / value basis)

Overseas Pharmaceuticals Sales trend

<Breakdown> (Millions of Yen)

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



FY2019 Forecasts
+8.3%

Increase forecasted with increasing Gel-One that compensate for a decline in SUPARTZ FX

U.S.

● Sales in the U.S.:

- **Gel-One** : Lifting our growth forecast
(+4% ⇒ +30% volume-based)
 - **SUPARTZ FX** : Lowering forecast owing to harsher market conditions and struggling local sales
(-3% ⇒ -15%, volume-based)
- ▶ **Seikagaku exports** : Gel-One revised upward because of higher shipments tied to favorable local sales SUPARTZ revised downward because of unfavorable local sales

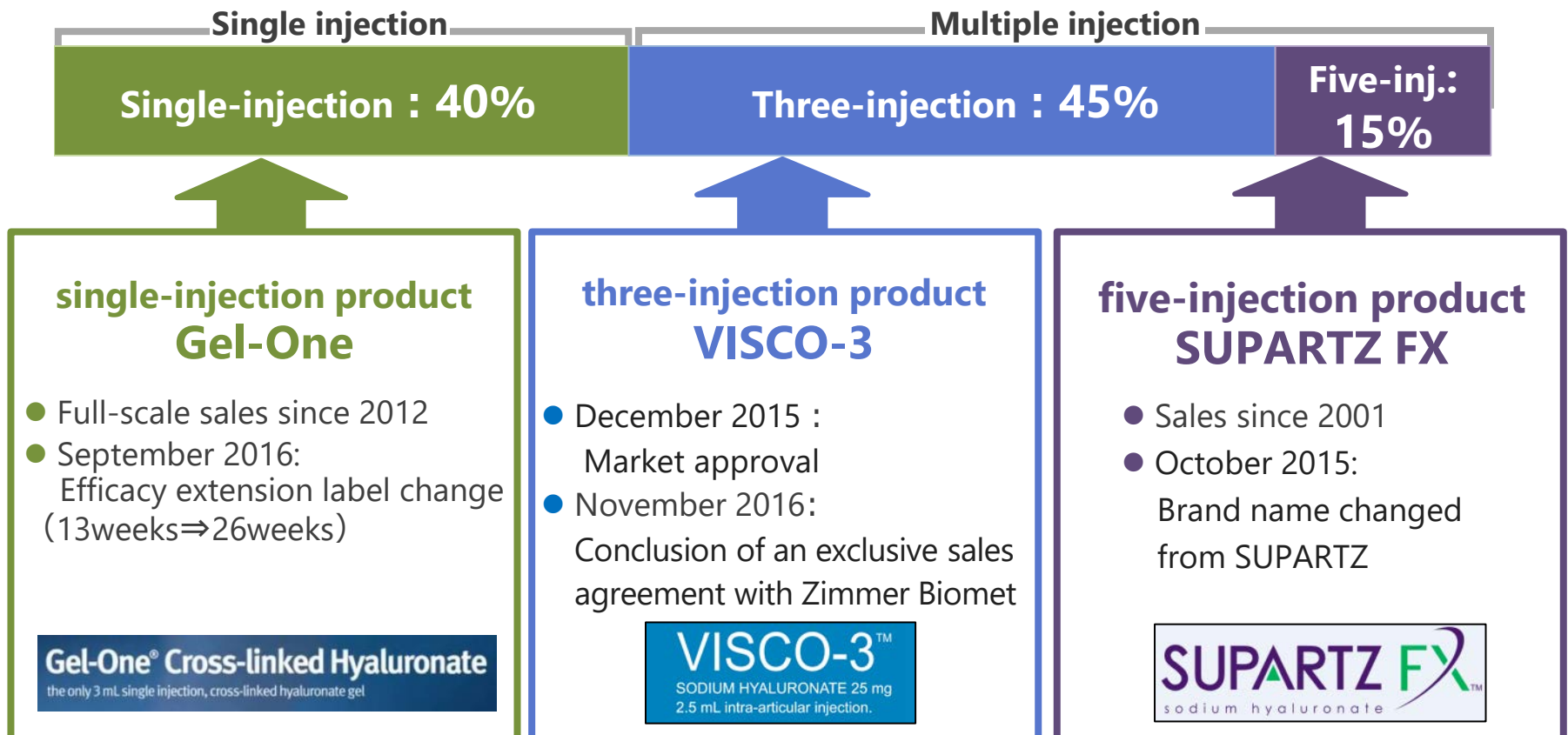
China, Other Regions

- **Local sales of ARTZ in China**
Trending as initially forecast (+7% , volume-based)
- ▶ **Seikagaku exports** :
Forecasted to be generally in line with initial forecast

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

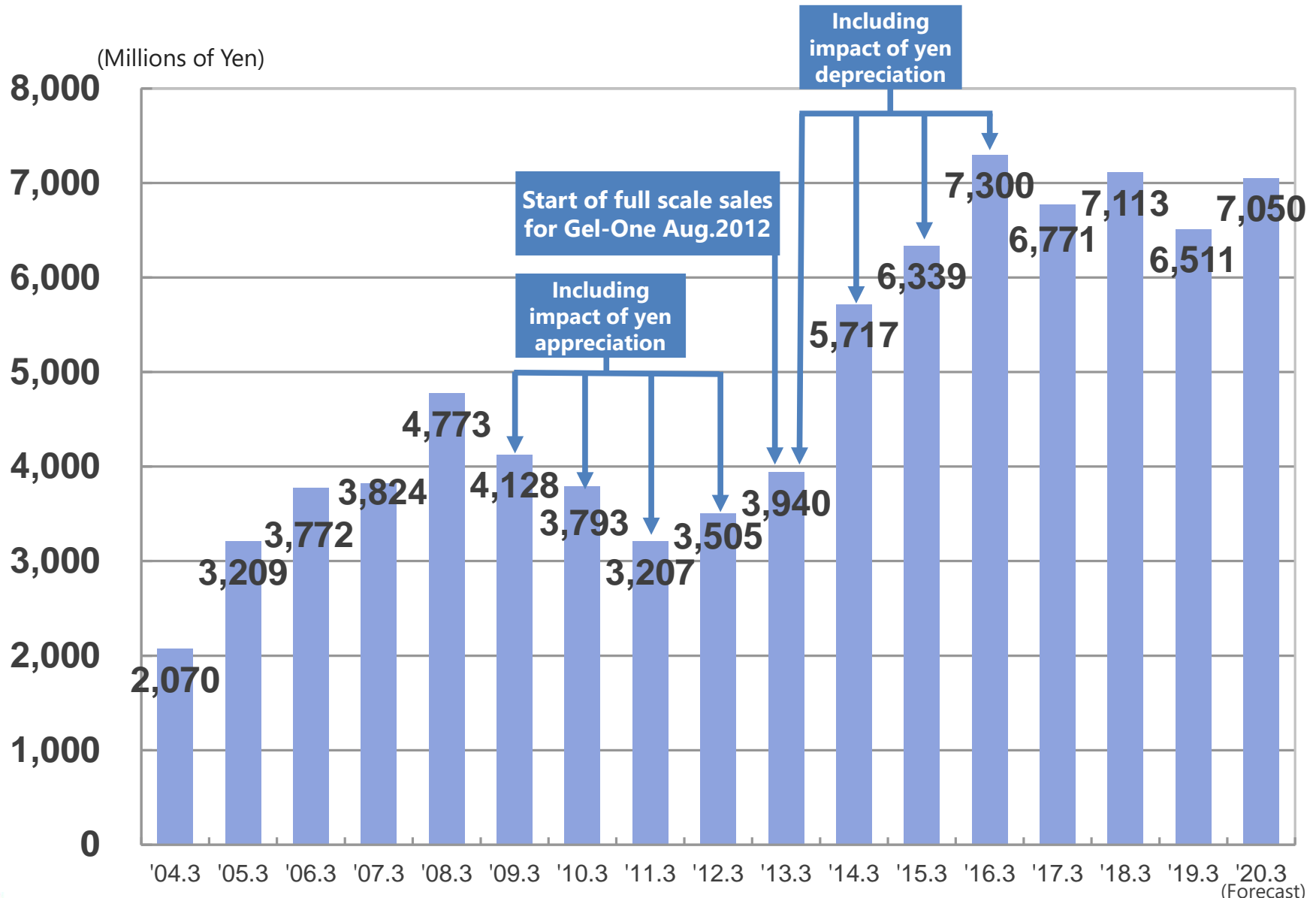
**Market size of US\$1,000 mil. in 2018 (-6.5% year-on-year)
The market contracted for the first time.**

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



*Figures for 2018, 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)

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



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



Exterior of the ACC offices



PYROCHROME®

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

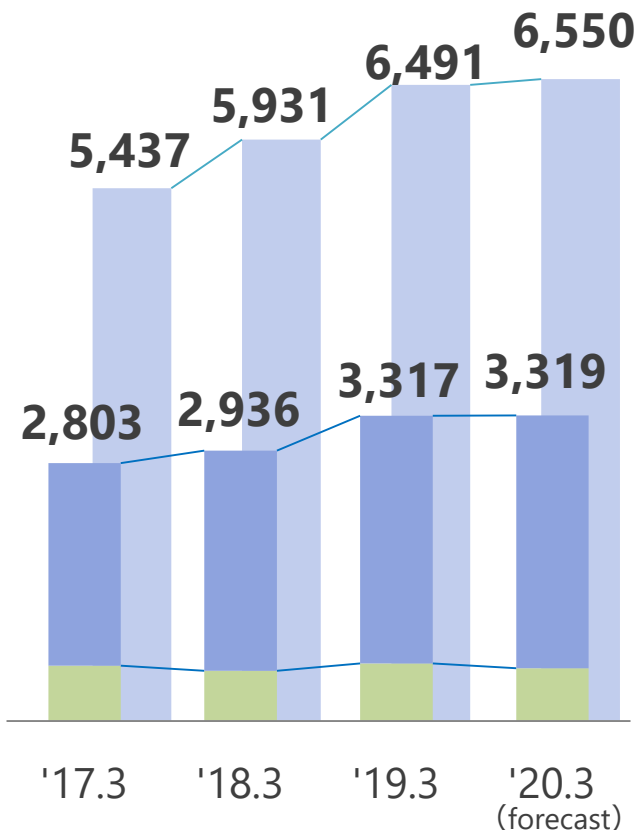
LAL Business Sales trend

(Millions of Yen)

■ Full year

<2Q Breakdown>

■ Overseas ■ Domestic



2Q FY2019 Results : +0.1% (Year-on-Year)

Overseas

* Foreign exchange impact: approx. -¥120million

Sales growing in bacterial Endotoxin Testing (BET) and Clinical Diagnostic (FungitellR) reagents (products used in diagnostics of fungal infections)

Domestic

A year-on-year decline in reaction to prior-period large volume sales of reagents and devices

FY2019 Forecasts : +0.9% (Year-on-Year)

Overseas

Increase forecasted due to enhanced sales activities by ACC

Domestic

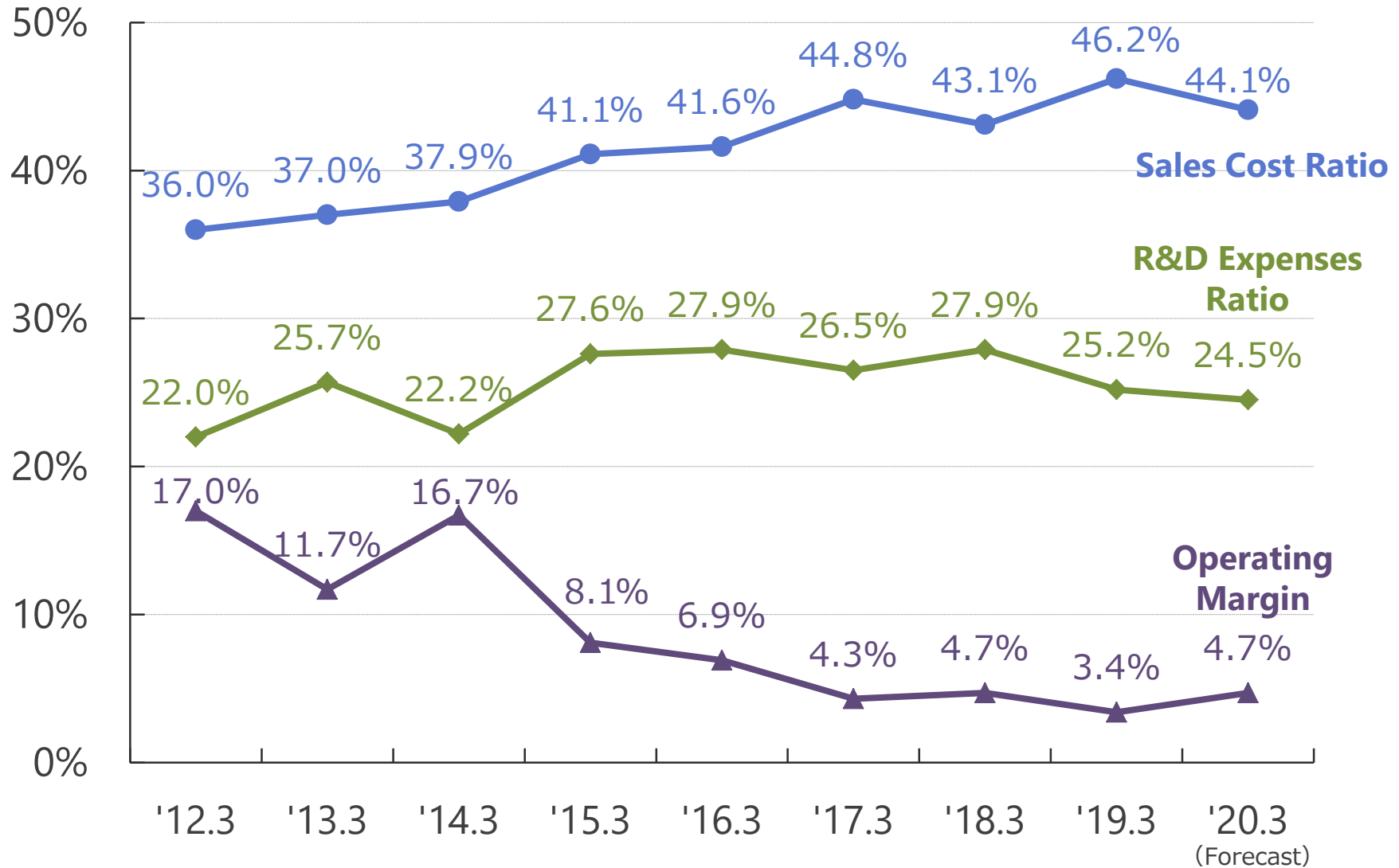
Forecast is generally at prior-year level

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).

* There is no change in forecast announced on November 8, 2019.

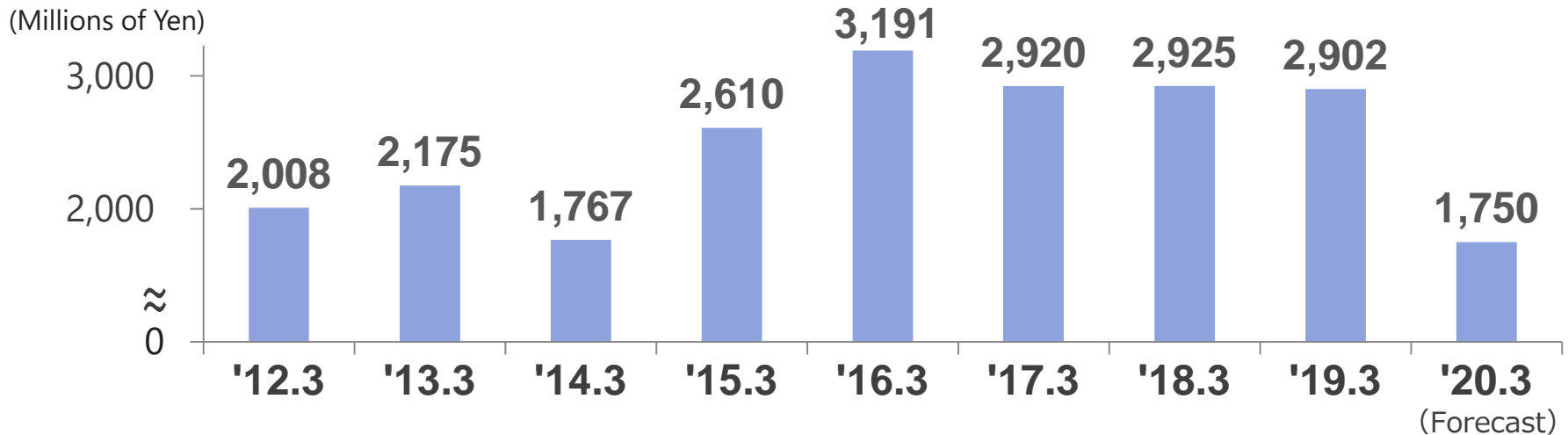
Trend in Financial Index



Trends in Depreciation & Capital Investments

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

■ Trend in Depreciation

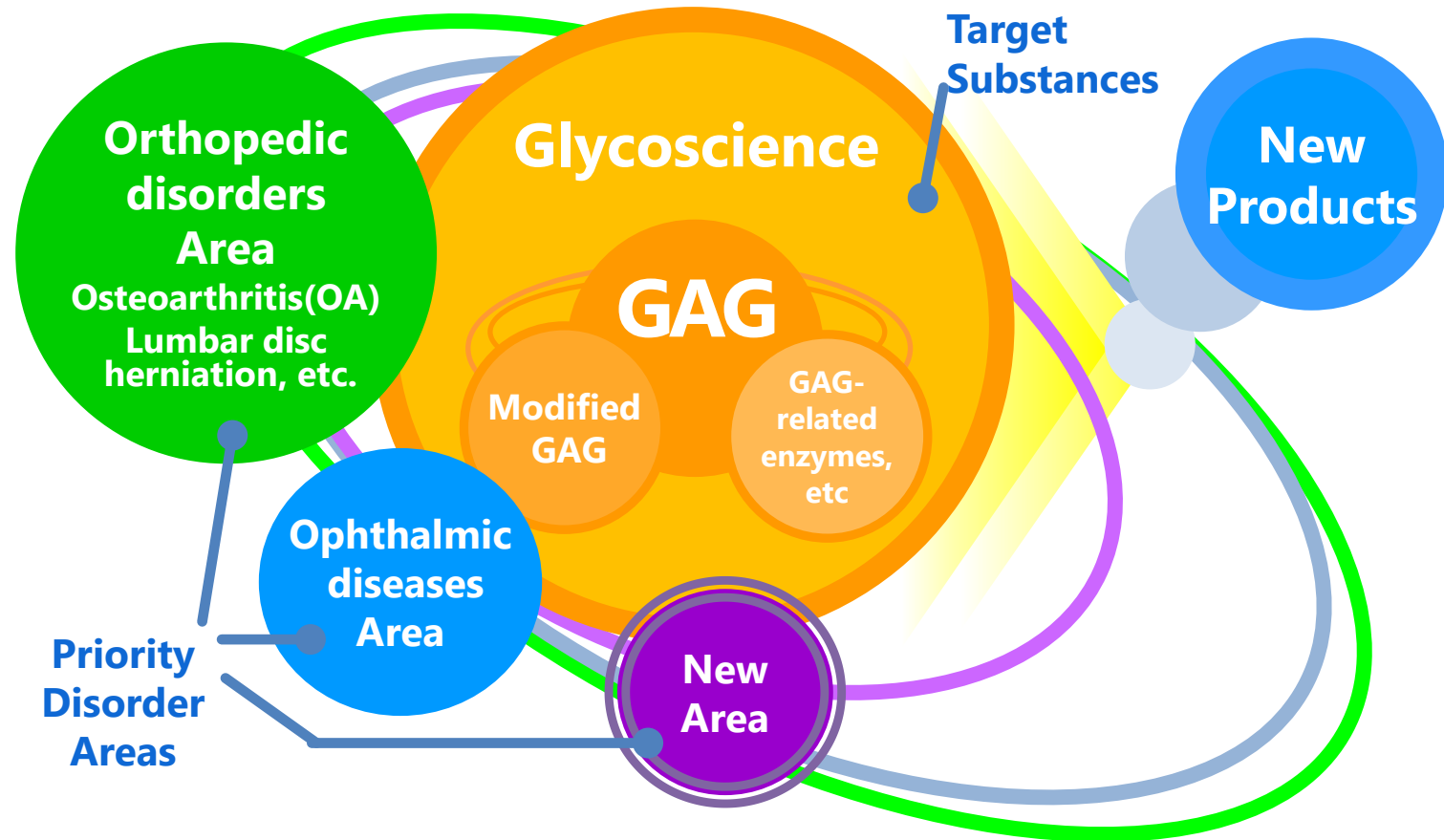


■ Trend in Capital Investments (Millions of Yen)

'12.3	'13.3	'14.3	'15.3	'16.3	'17.3	'18.3	'19.3	'20.3 (Forecast)
5,718	9,164	7,222	2,095	1,975	1,173	1,591	1,310	2,400

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**

GAG

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

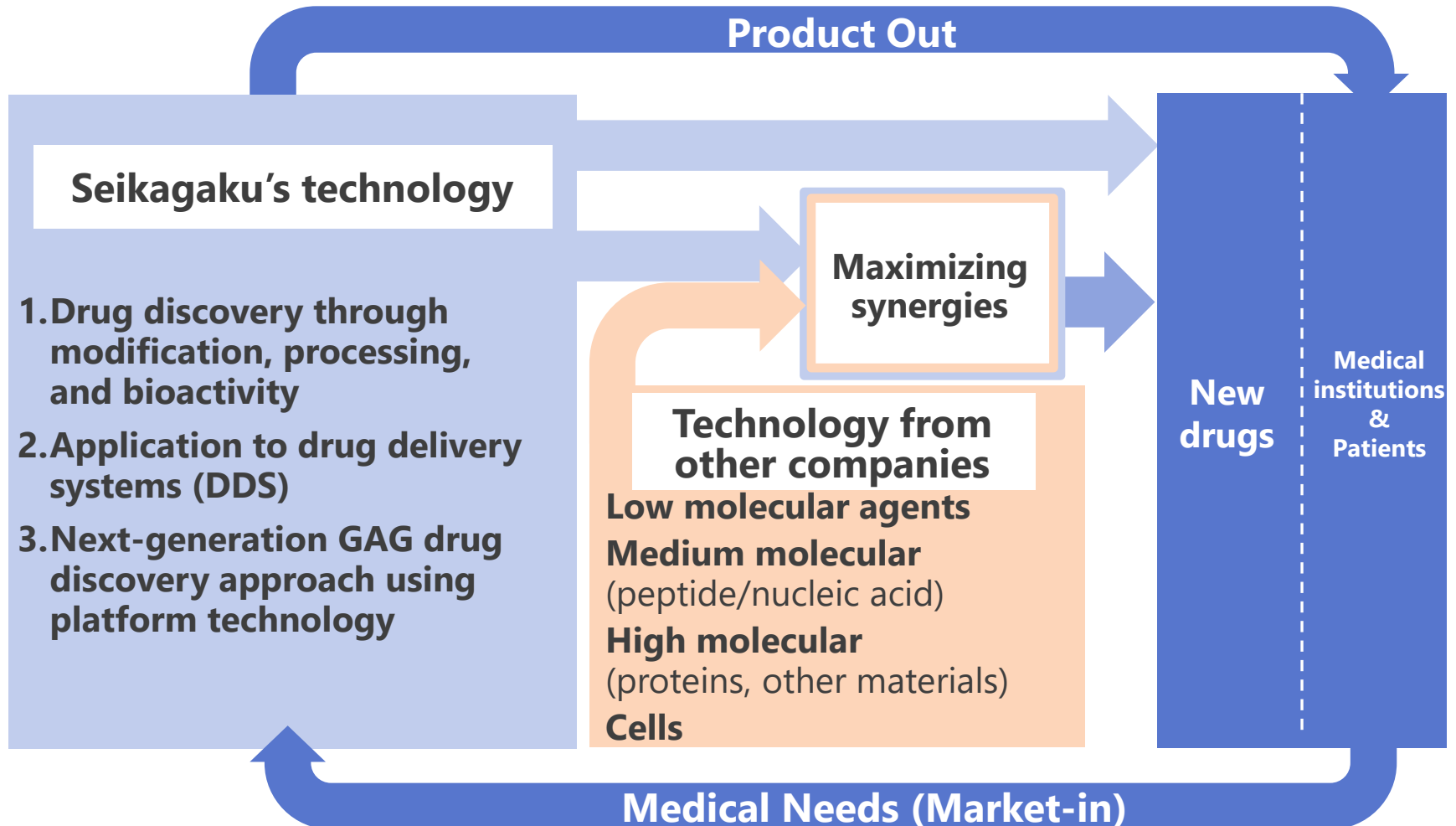
- Conversion from natural GAG **to fermented GAG**
- Expanding the field of sugar chain drug discovery Applying to glycobiology

**SI-613
SI-614**

New Drugs

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



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

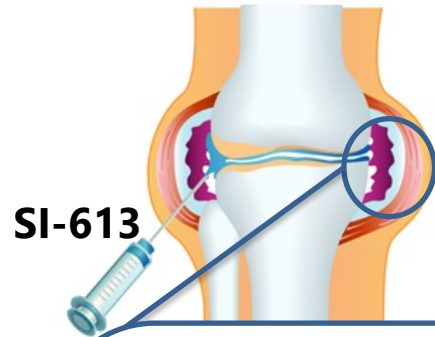
- No major concern such as adverse reactions was observed: **Confirmed safety of SI-6603**

Improvement at alleviation of leg pain (Subjective indicator)

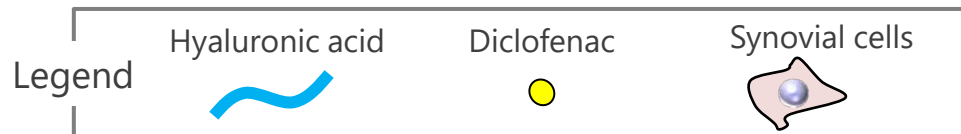
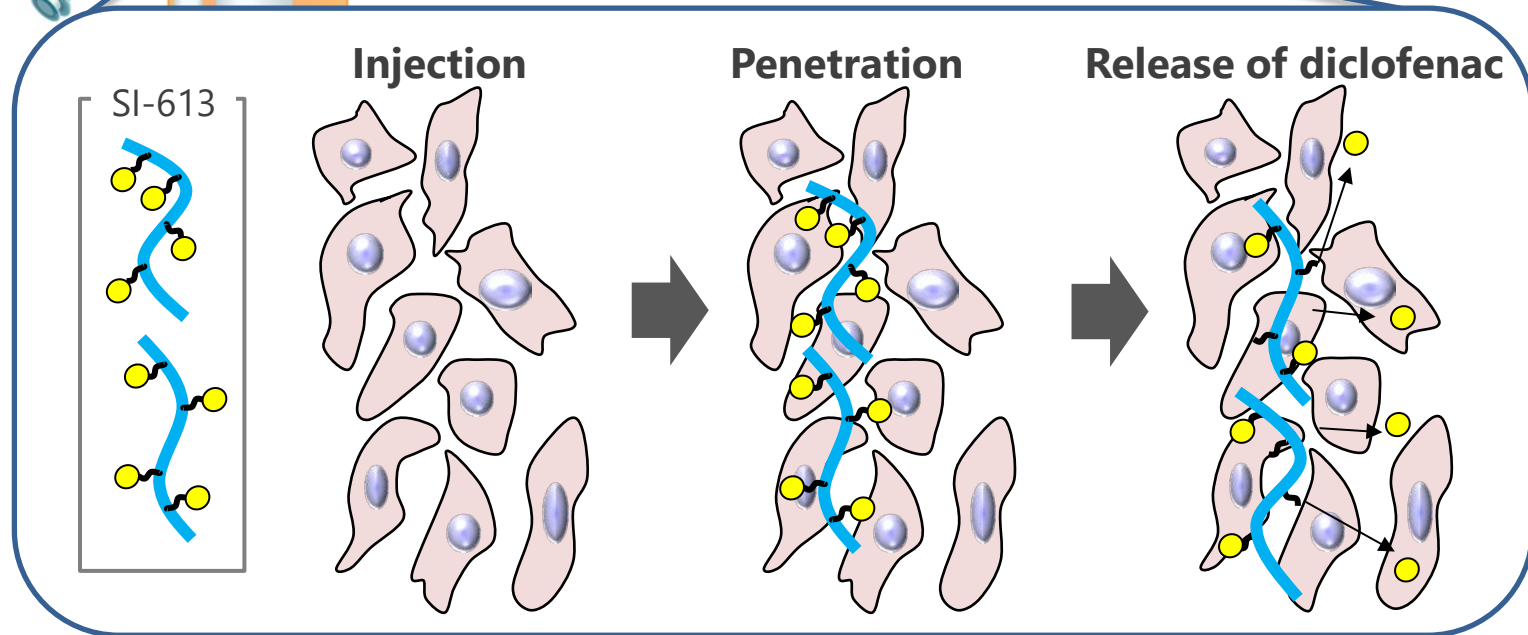
- Statistically significant improvement of leg pain at 13 weeks by VAS was not demonstrated
- ▶ ① There is a guideline for diagnostic and pathology of lumbar disc herniation in Japan, however there is no widely used guideline in the U.S. Therefore, there is possibility that some patients out of Japanese 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

Sustained Release of Diclofenac in SI-613

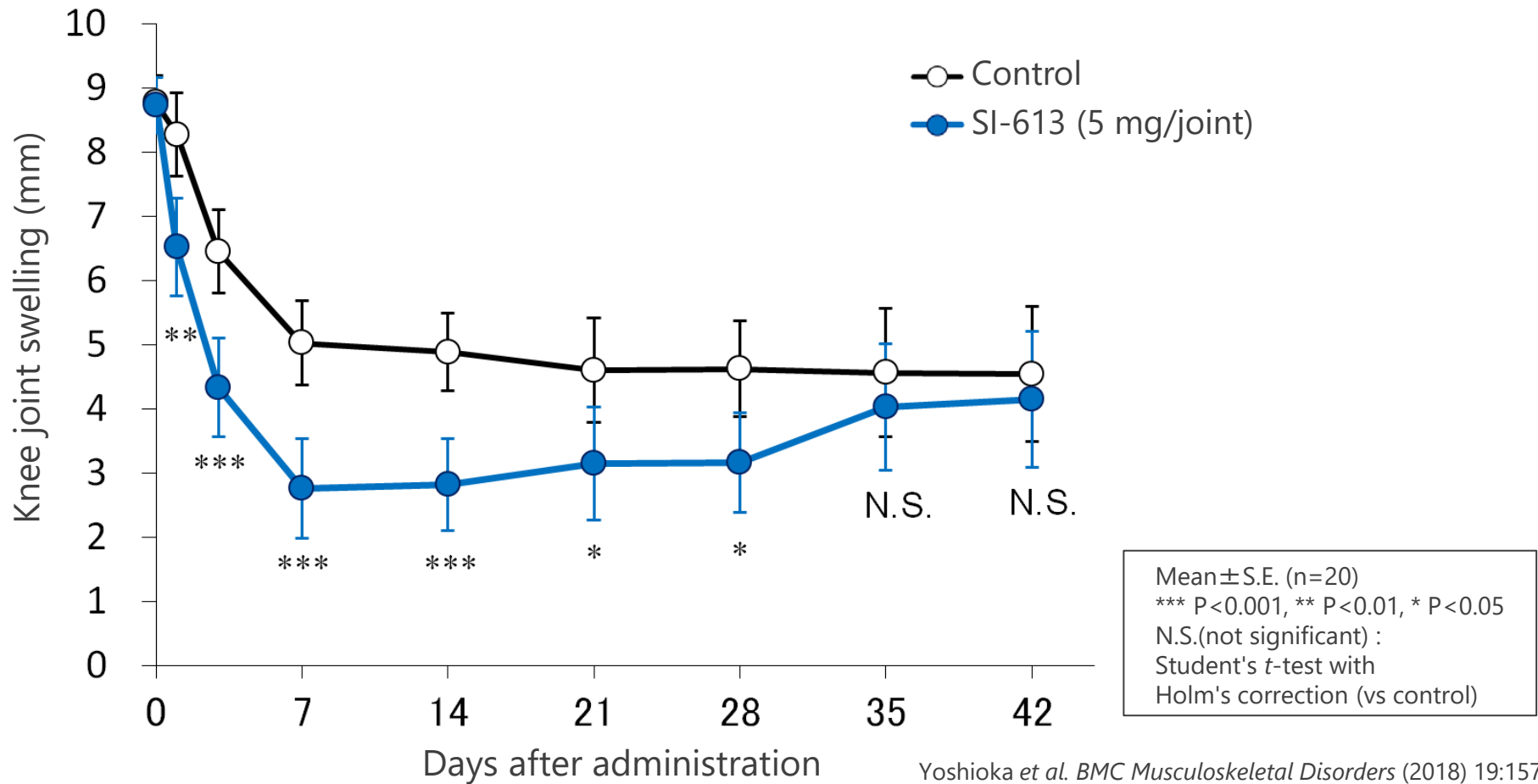


SI-613 (substance name: hyaluronic acid-diclofenac conjugate) is thought to penetrate the synovial membrane (connective tissue within the articular capsule) and gradually release diclofenac



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



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

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: Application

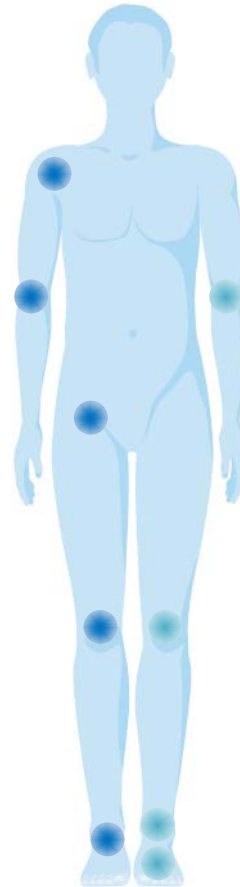
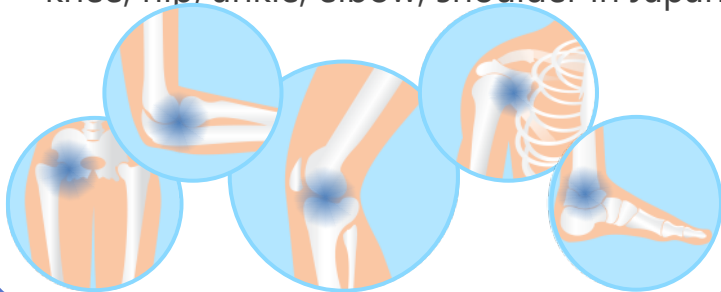
A disease in which joint tissue deteriorates due to abrasion of the articular cartilage, leading to inflammation and pain

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: PIIb

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:

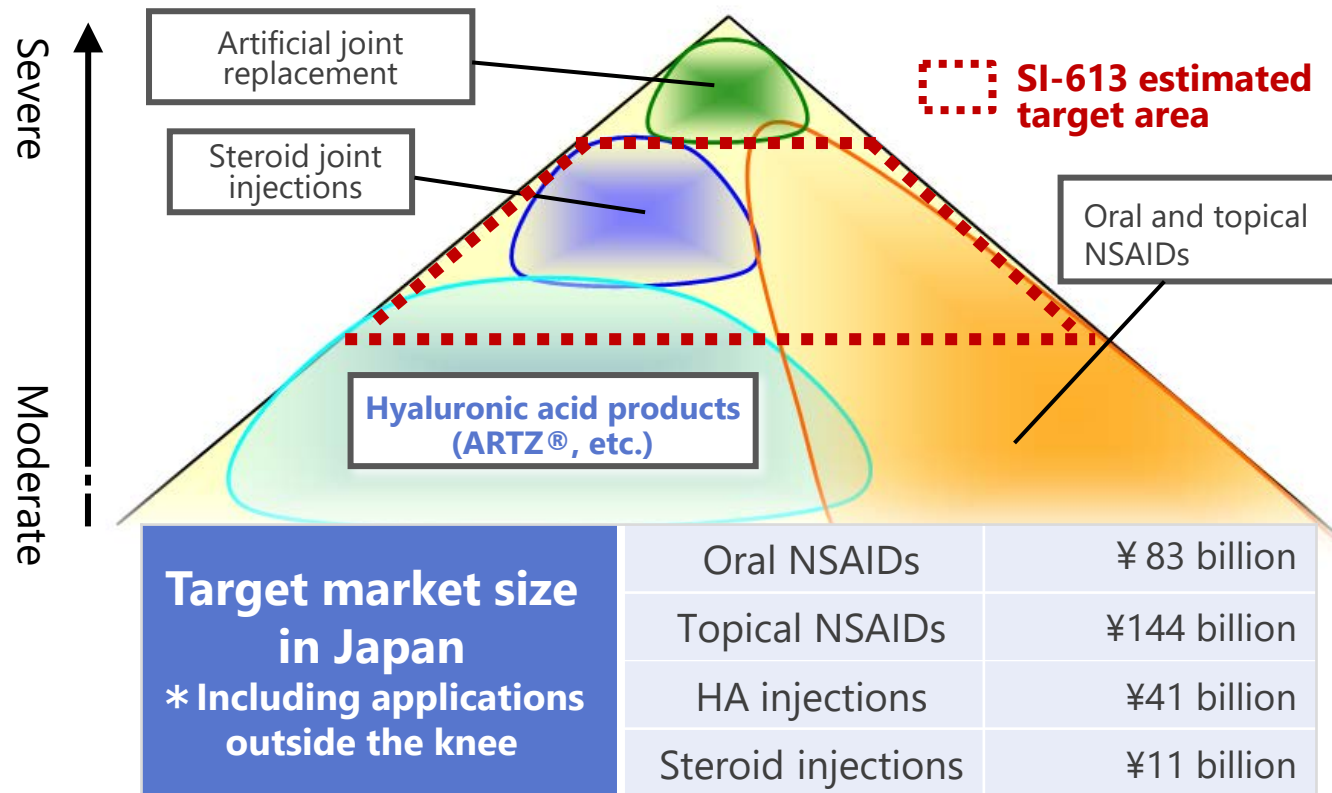
Approx. 0.9 million

(Seikagaku estimate for the above four diseases in Japan)



SI-613 Estimated Target Patients

Quickly fostering approval and launching
as a new core product



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

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	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	—
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	—	—

Our Three Important Measures

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

- Strengthening and making use of the Company's own GAG-related core technology related to GAGs
- Accelerating innovative drug discovery using the Open Innovation strategy
- Steady progress of the development pipeline with an eye towards global expansion

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

- Post-marketing of HERNICORE in Japan
- Accelerating multinational expansion of existing products and products in development
- Global expansion of endotoxin-detecting reagents that leverage genetic recombination technology

III. Productivity improvement reforms

- Thorough cost reductions
- Diversifying the profit model
- Creating an organization for maximizing the value of resources

**A period to solidify our foundation
in order to lay out a path for revived growth**

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%

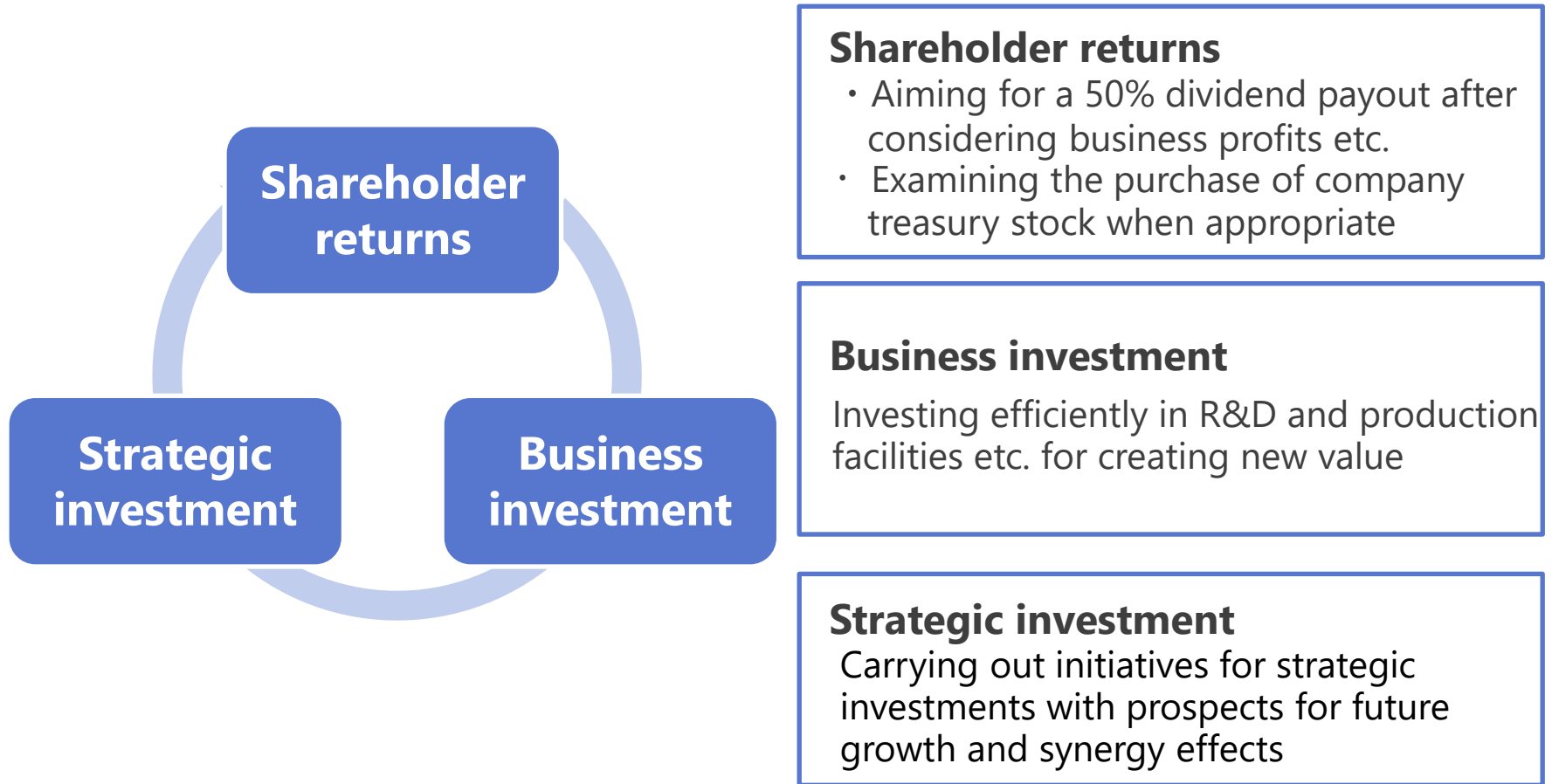
« Assumptions »

- 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



* 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 77.1%

Ophthalmic Surgical Aids



Bulk Products



Domestic
Pharmaceuticals
→ 49.9%

Joint Function
Improving Agents



Overseas
Pharmaceuticals
→ 22.9%



Net Sales
28,384million
(FY2018 Results)

Bulk Products
→ 4.3%

LAL
Business
22.9%

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.



<https://www.ehiza.jp/>



SEIKAGAKU CORPORATION

Copyrights(C)2019 SEIKAGAKU CORPORATION. All rights reserved.