Exploring the Innovative Promise of Glycoscience

Financial Results for the Fiscal Year 2019

SEIKAGAKU CORPORATION

(TSE:4548)

Contents

< 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.

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
- Once the spread of infection settles down, attention will focus on recruitment of subjects, and the test plan will be re-evaluated

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

Overview of Fiscal Year 2019

(Millions of Yen)	FY2019 Results	Year-on-Year		Comparison with Revised Forecasts（11/8）	
		Change	% of Change	Change	% of Change
Net sales	28,642	+258	+0.9%	+42	+0.1%
Operating Income	1,960	+983	+100.6%	+610	+45.2%
Ordinary Income	3,981	+1,121	+39.2%	+231	+6.2%
Extraordinary loss	-13,524	-13,524	–	-25	–
Net Income	-10,839	-13,084	–	+160	–
R&D Expenses (Ratio to net sales)	6,877 (24.0%)	-271 (-1.2pt)	-3.8%	-122 (-0.5pt)	-1.8%
Average Exchange Rate (1US$)	¥108.75	-¥2.16			

	FY2019 Results	FY2018 Results	FY2019 Revised Forecasts
Net Income per Share	-¥192.15	¥39.76	-¥194.99
R O E	-16.3%	3.1%	
SKK EBITDA*	5,675million yen	4,620million yen	

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

Net sales by Business Segment (FY2019)

(Millions of Yen)	FY2019 Results	Year-on-Year	% of Change
Net sales	28,642	+258	+0.9%
Pharmaceuticals	22,166	+272	+1.2%
Domestic Pharmaceuticals	13,679	-482	-3.4%
Overseas Pharmaceuticals	7,466	+955	+14.7%
Bulk Products	1,019	-200	-16.4%
LAL Business	6,476	-14	-0.2%
(Overseas sales)	12,913	+947	+7.9%

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

Domestic Pharmaceuticals

▶ ARTZ (Joint-function improving agent)

- Sales decreased due to the NHI drug price revision (Oct. 2019) accompanying the consumption tax increase

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

▶ OPEGAN series (Ophthalmic viscoelastic devices)

- Sales increase as favorable results are maintained in acquiring share from competing products to cover the NHI drug price revisions

▶ MucoUp

(Submucosal injection agent for endoscopic surgery)

- Sales decline due to impact from introduction of a competing products

▶ HERNICORE

(Treatment for lumbar disc herniation)

- Sales decreased due to high shipments to secure distribution inventory in the previous fiscal year

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

Net sales by Business Segment (FY2019)

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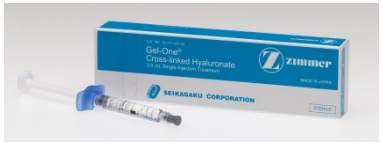
海外医薬品

*Foreign exchange impact on Overseas Pharmaceuticals: approx. -180 million yen

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

- Sales up substantially due to qualification for preferential reimbursement status with multiple insurers and the sales partner to promote switching from competing products
- Shipments were down in March 2020 due to COVID-19 infection, but small impact on full-year results



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

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

- Trend continues toward preference for products that allow a low number of injections
- Sales decrease from lower local sales volume

▶ ARTZ in China (Multiple injection)

- Although local sales volume was rising, sales decreased due to restrictions on outpatient services at medical institutions in response to the spread of COVID-19 infection

Net sales by Business Segment (FY2019)

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Bulk Products

- Sales decline due to intense competition in hyaluronic acid

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

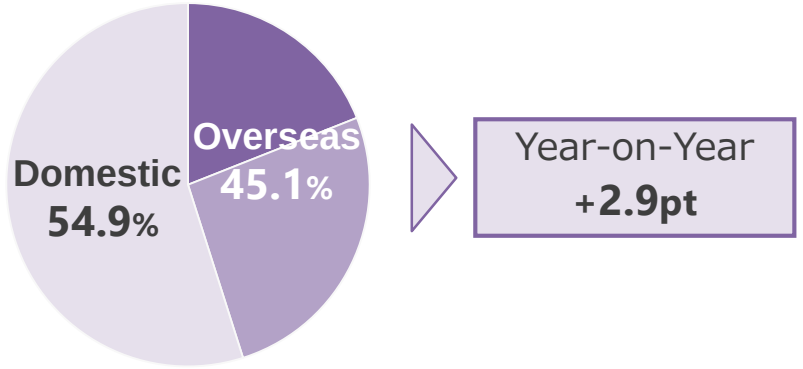
LAL Business

*Foreign exchange impact on LAL Business: approx. -70 million yen

- At previous-year level as strong overseas sales compensate 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



Income in FY2019 (Year-on-Year)

(Millions of Yen)	FY2019 Results	Year-on-Year	% of Change
Net sales	28,642	+258	+0.9%
Cost of Sales (Cost of Sales ratio)	12,513 (43.7%)	-600 (-2.5pt)	-4.6%
SGA expenses	14,169	-123	-0.9%
R&D Expenses (to Net sales ratio)	6,877 (24.0%)	-271 (-1.2pt)	-3.8%
Operating Income (to Net sales ratio)	1,960 (6.8%)	+983 (+3.4pt)	+100.6%
Ordinary Income	3,981	+1,121	+39.2%
Extraordinary loss	-13,524	-13,524	–
Net Income	-10,839	-13,084	–
Depreciation	1,778	-1,124	-38.7%

Operating Income

Cost of Sales Ratio （-2.5pt）

- Decrease in depreciation in connection with impairment loss*

SGA Expenses（-123）

- Drop in R&D expenses due to completion of clinical studies in Japan for SI-613, a treatment for osteoarthritis
- Cost reduction of sales promotion expenses

Ordinary Income

Non-operating Income / Expenses（+138）

- Increased royalty income (+1,195)
- Gain and loss on sales of investment securities (−983
- Foreign exchange losses rise (-103)

Net Income

Extraordinary loss （-13,524）

- Recording of impairment loss*

*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

Income in FY2019 (Revised Forecasts 11/8)

(Millions of Yen)	FY2019 Results	Compa. with revised forecasts	% of Change
Net sales	28,642	+42	+0.1%
Operating Income (to Net sales ratio)	1,960 (6.8%)	+610 (+2.1pt)	+45.2%
Ordinary Income	3,981	+231	+6.2%
Extraordinary loss	-13,524	-25	–
Net Income	-10,839	+160	–
Cost of Sales ratio	43.7%	-0.4pt	–
R&D Expenses (to Net sales ratio)	6,877 (24.0%)	-122 (-0.5pt)	-1.8%
Depreciation	1,778	+28	+1.6%

Net sales

While domestic pharmaceutical sales declined, overseas pharmaceutical sales trended steady, bringing overall sales in line with forecasts

Pharmaceuticals（+116）

LAL Business（-73）

Operating Income

Cost of Sales Ratio（-0.4pt）

- Trending in line with expectations

SGA Expenses（-480）

- Delay in R&D expenses and selling-related costs

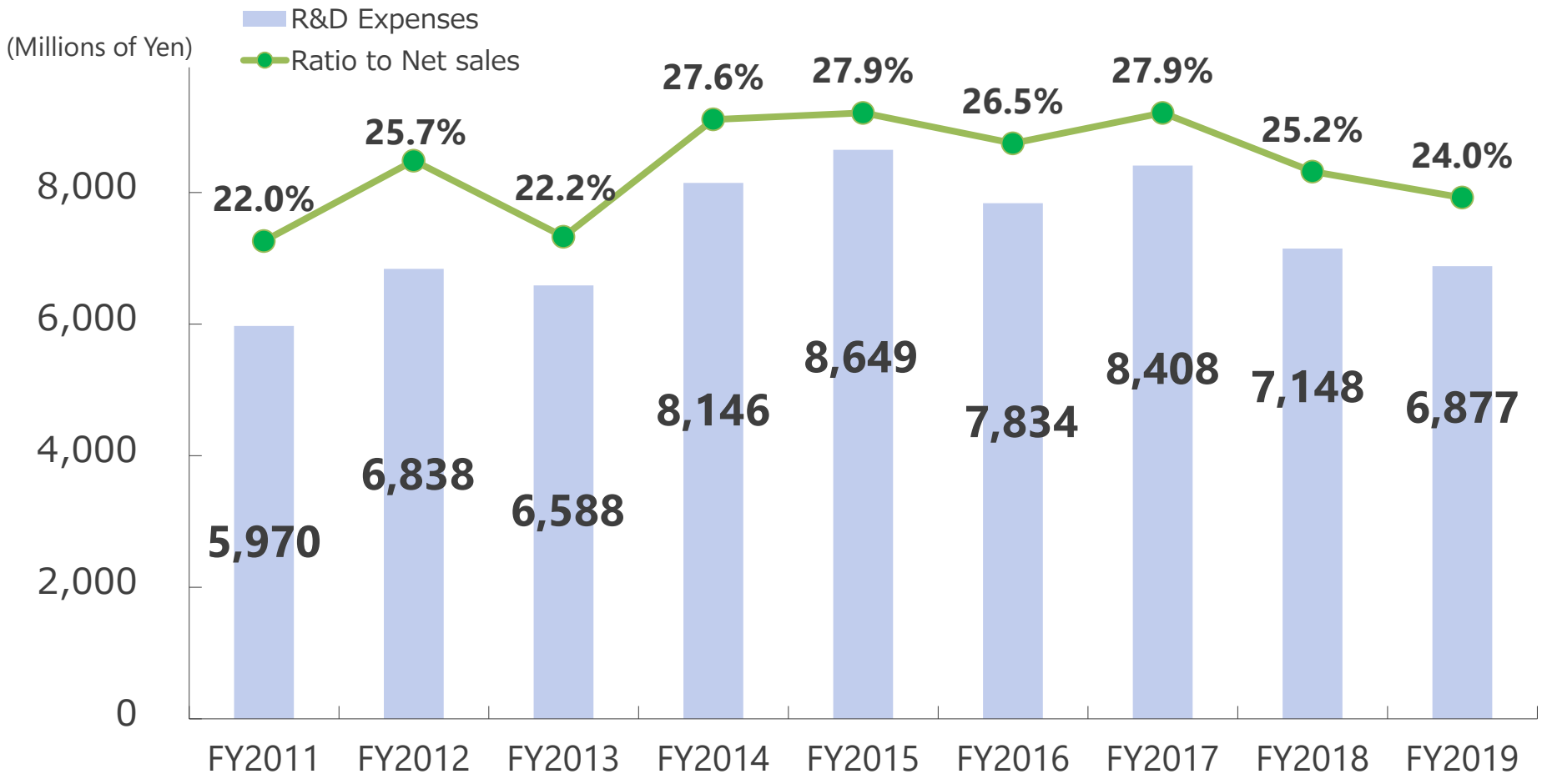
Net Income

Non-operating Income / Expenses（-379）

- Loss taken on sales of investment securities

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）

● FY2019 Results

- Market share increases as successful measures to acquire new user facilities see success
- Market shrinks and deliveries to medical institutions undergo a sales slump as applications expand for externally and internally administered medicines and COVID-19 infection exerts an impact

growth rate：-0.7%
Market growth rate：-1.8%
Market share ：59.9%
(+0.7pt)

▶ FY2020 Measures

- Continuing to aim for share expansion due to switching from competing products

OPEGAN（Ophthalmic viscoelastic devices）※including SHELLGAN

● FY2019 Results

- Aggressively furnishing product feature information
- Taking share from competing products and shipment interruptions for other companies' products leads to a temporary increase in deliveries to medical institutions

growth rate：+21.4%
Market growth rate：+13.4%
Market share ：47.1%
(+3.1pt)

▶ FY2020 Measures

- Strengthening measures to induce switching from competing products and aiming to maintain accounts acquired in fiscal 2019

HERNICORE （Treatment for lumbar disc herniation）

● FY2019 Results

- Market penetration proceeding steadily as deliveries to medical institutions increase
- Since November 2019, emergency facilities have been available through without full-time supervisory physicians at the JSSR

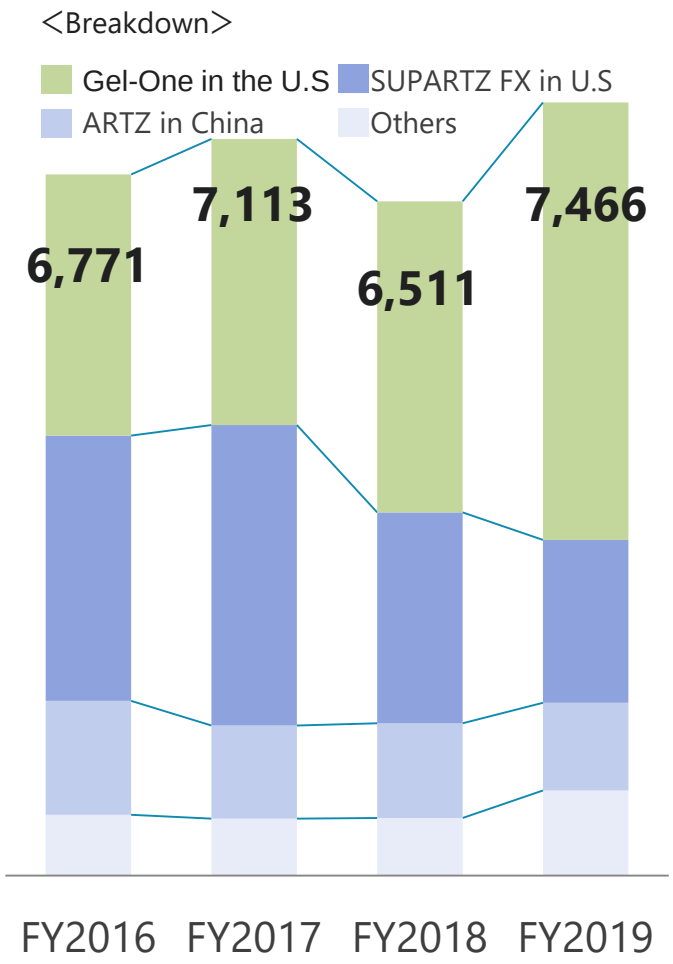
▶ FY2020 Measures

- Promoting proper use and appropriately implementing the compiling of safety information

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

Overseas Pharmaceuticals Sales trend

(Millions of Yen)



FY2019 Results +14.7%

Gel-One is trending firm
China ARTZ declining due to impact of COVID-19 infection

U.S.

● Sales in the U.S.

Gel-One : Increase due to qualification for preferential reimbursement status with multiple insurers, and the sales partner to promote switching from competing products (+30% volume-based)

SUPARTZ FX : Decline as trends continue towards selection of products requiring few injections (-20% volume-based)

▶ Seikagaku exports

An increase as SUPARTZ FX declines due to local sales drop and inventory adjustments, but major growth at Gel-One compensates

▶ FY2020 Measures

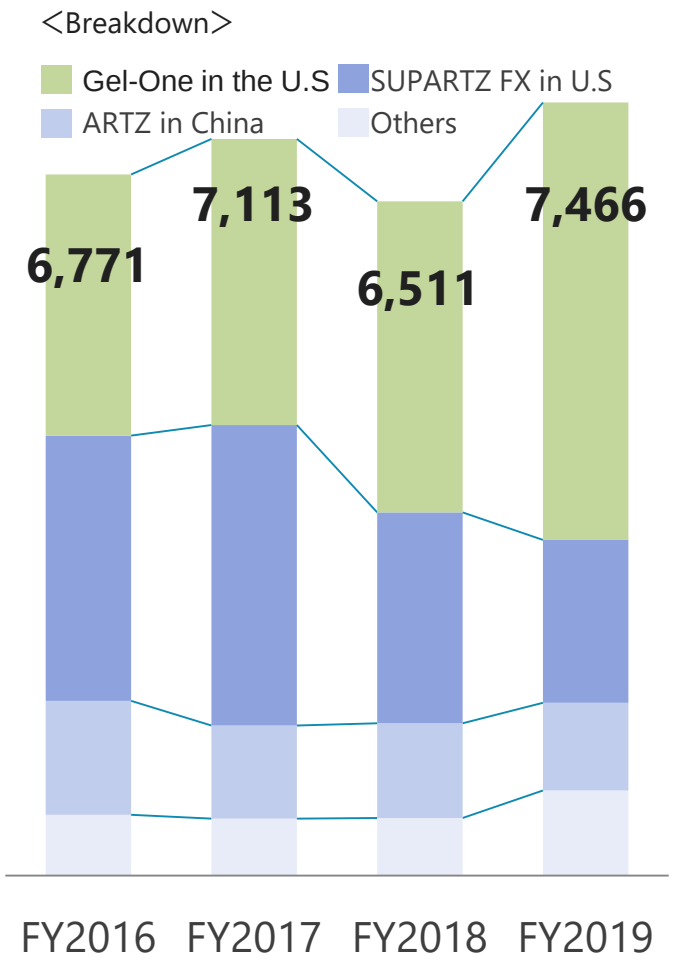
Gel-One : Grow local sales through enhanced access to targeted physicians and qualifying for preferred reimbursement status with multiple insurers

SUPARTZ FX : Differentiate from other 5-injection products, patient awareness campaigns, direct-to-consumer ads, strengthen tie-ups with patient groups, other activities to shrink declines

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

Overseas Pharmaceuticals Sales trend

(Millions of Yen)



FY2019 Results +14.7%

Gel-One is trending firm
China ARTZ declining due to impact of COVID-19 infection

China, Other Regions

● Local sales of ARTZ in China

Sales decline due to control on clinic visits due to the expanding COVID-19 infection

(-17% volume-based)

▶ Seikagaku exports

An increase due to growth for Taiwan and Italy, despite lower shipments of China ARTZ

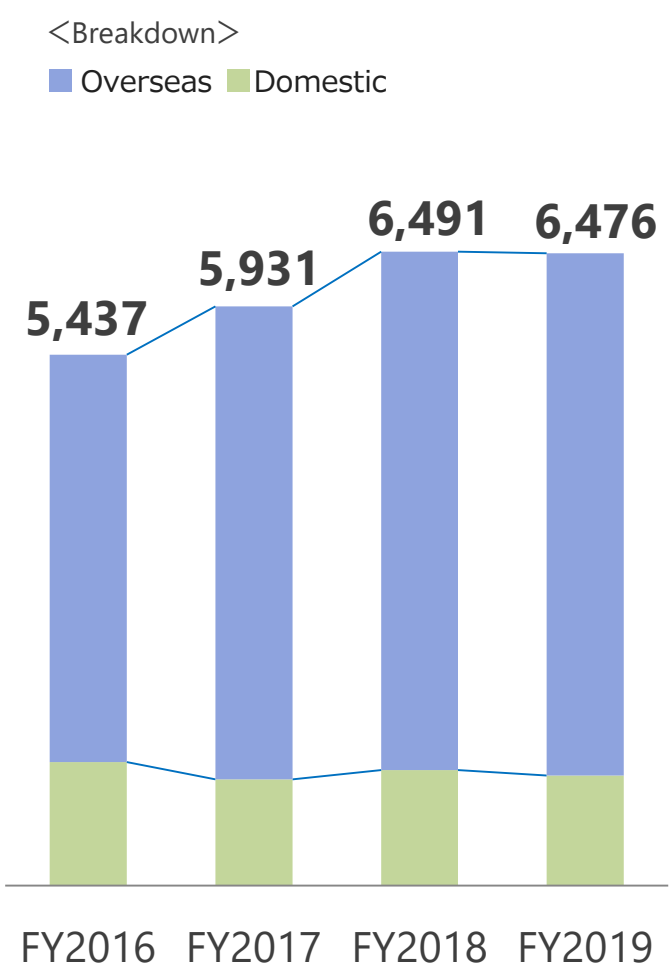
▶ FY2020 Measures

Maintain sales to large hospitals in major cities and continue to develop in peripheral cities and for mid-size clinics and hospitals

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

LAL Business Sales trend

(Millions of Yen)



FY2019 Results : - 0.2% (Year-on-Year)

＊Foreign exchange impact: approx. - ¥70million

Overseas

Sales are up for sales of Bacterial Endotoxin Testing (BET) and Clinical Diagnostic (Fungitell) reagents due to enhanced sales activities at overseas subsidiary ACC

Domestic

Sales down due to snapback from large previous-year reagent sales and impact of selling-period adjustments

FY2020 Measures

At ACC, planning to expand product lineup with an aim for developing new markets

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).

Forecasts for Fiscal 2020

Fiscal 2020 financial forecasts

Continuing to carefully examine the impact of COVID-19 infection on financial results, and will promptly make an announcement once it becomes possible to disclose the earning forecast

Business impacted by COVID-19 infection novel coronavirus

Pharmaceutical Business

Domestic pharmaceuticals

- Forecasting a decline in deliveries to medical institutions due to curtailment of outpatient services and recommendations to delay surgeries

Overseas pharmaceuticals

- Forecasting a decrease in local sales because of guidance to postpone non-urgent medical procedures

LAL Business

- No significant impact has emerged at this time, but if voluntary restraint on economic activity is prolonged, then business may be affected

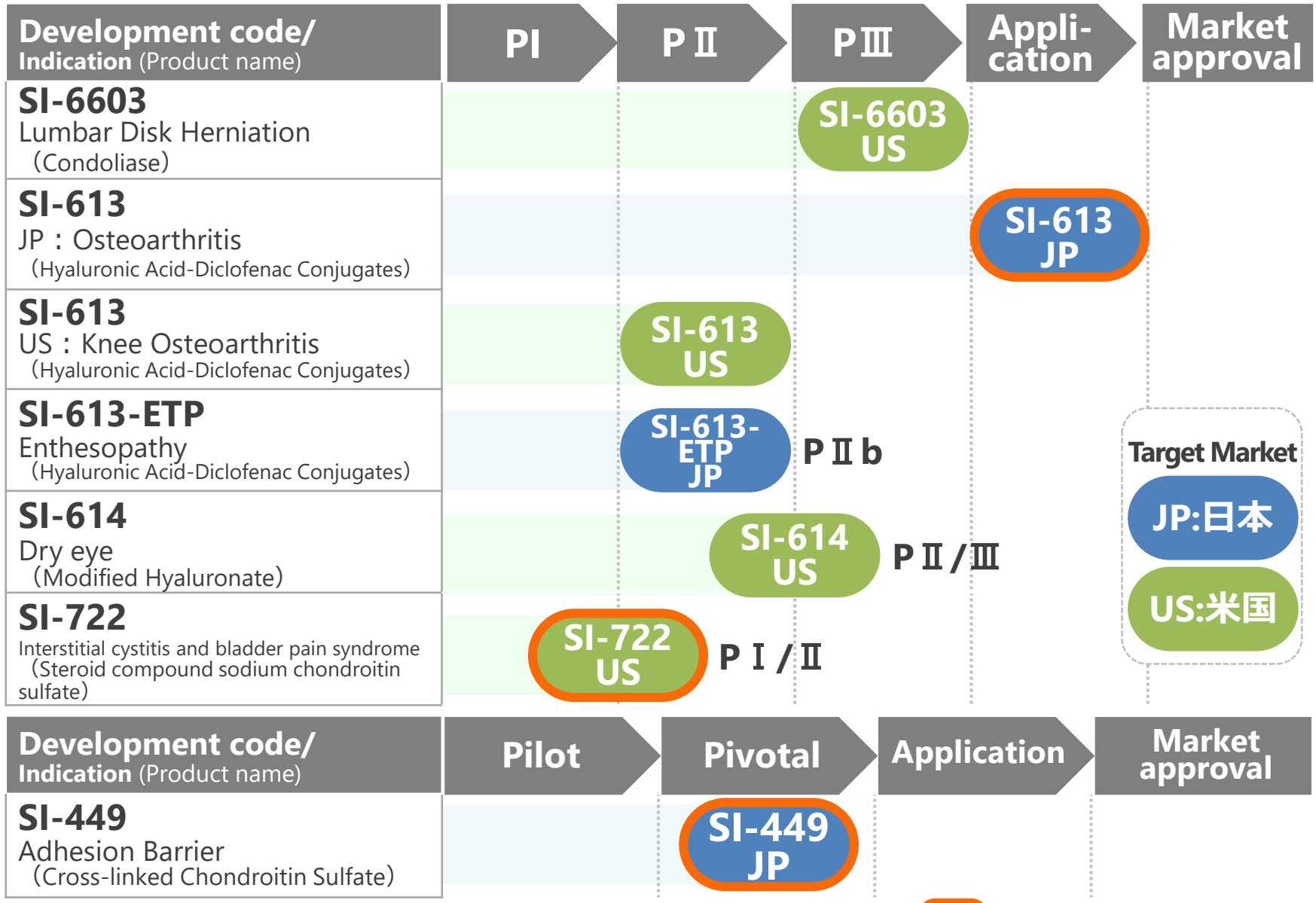
R&D

- Delayes in progress of clinical studies may affect the timing of recognition of R&D expenses

Other Assumptions

- NHI drug price reduction (from April 2020) ARTZ -13.1%, OPEGAN -1.7%
- Financial results of Dalton, now a consolidated subsidiary, to be reflected in the Pharmaceutical Business segment

Pipeline List (Research and Development themes)



：changes from the FY2018

SI-6603 (Treatment for Lumbar Disc Herniation)

Prioritizing additional clinical studies to raise probability of success; extending the study period

Development status

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

Intiated 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

➢ 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

⇒Planning to review the study plan due to effect of COVID-19 infection

SI-613 (Treatment of Osteoarthritis/Enthesopathy)

Submitted a new drug application for manufacturing and marketing approval in Japan (osteoarthritis)
Agreement with Eisai on a co-development and marketing alliance in China

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

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**

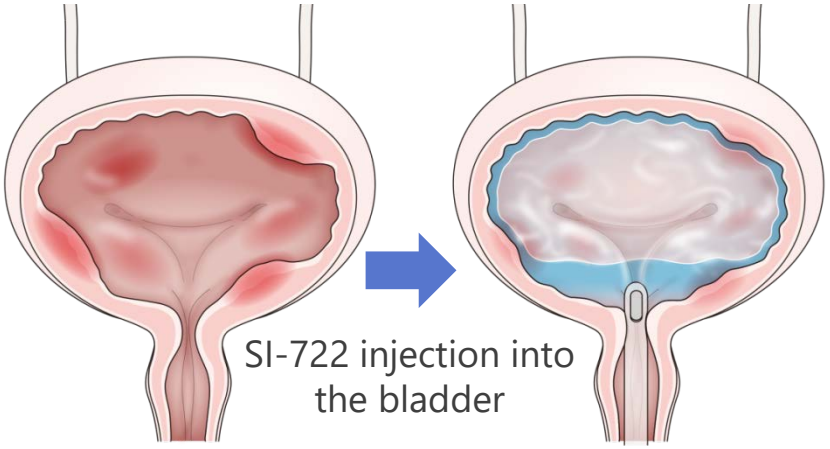
SI-613-ETP (enthesopathy) Japan

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

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**
- **Started subject administration in March 2020**
- Study completion expected during FY2020

⇒**Planning to review clinical study plan due to effects of COVID-19 infection**

＊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

<SI-722 summary>

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

Indication : Interstitial cystitis and bladder pain syndrome

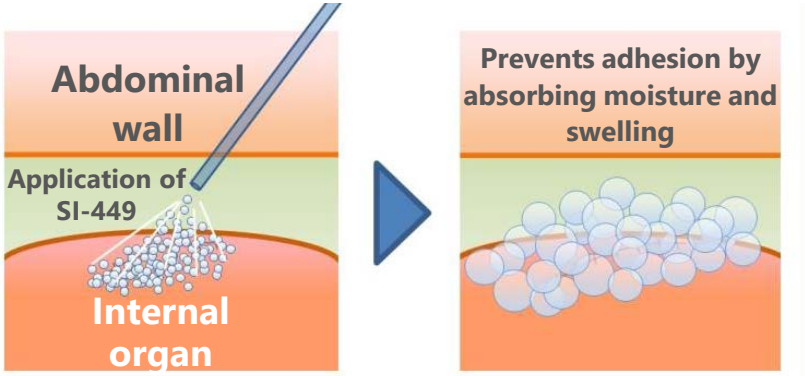
Method of use : Injection into the bladder

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

SI-449 (Adhesion Barrier / Medical Device)

Confirming useful effects in pilot study
Starting pivotal study in May 2020

SI-449 Administration image



Development status

- **Japan pivotal study**
  - **Starting May 2020**
  - Evaluated for effectiveness, safety, and usability
  - **Start time for subject enrollment under careful review in consideration of COVID-19 infection status**
- 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)

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

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

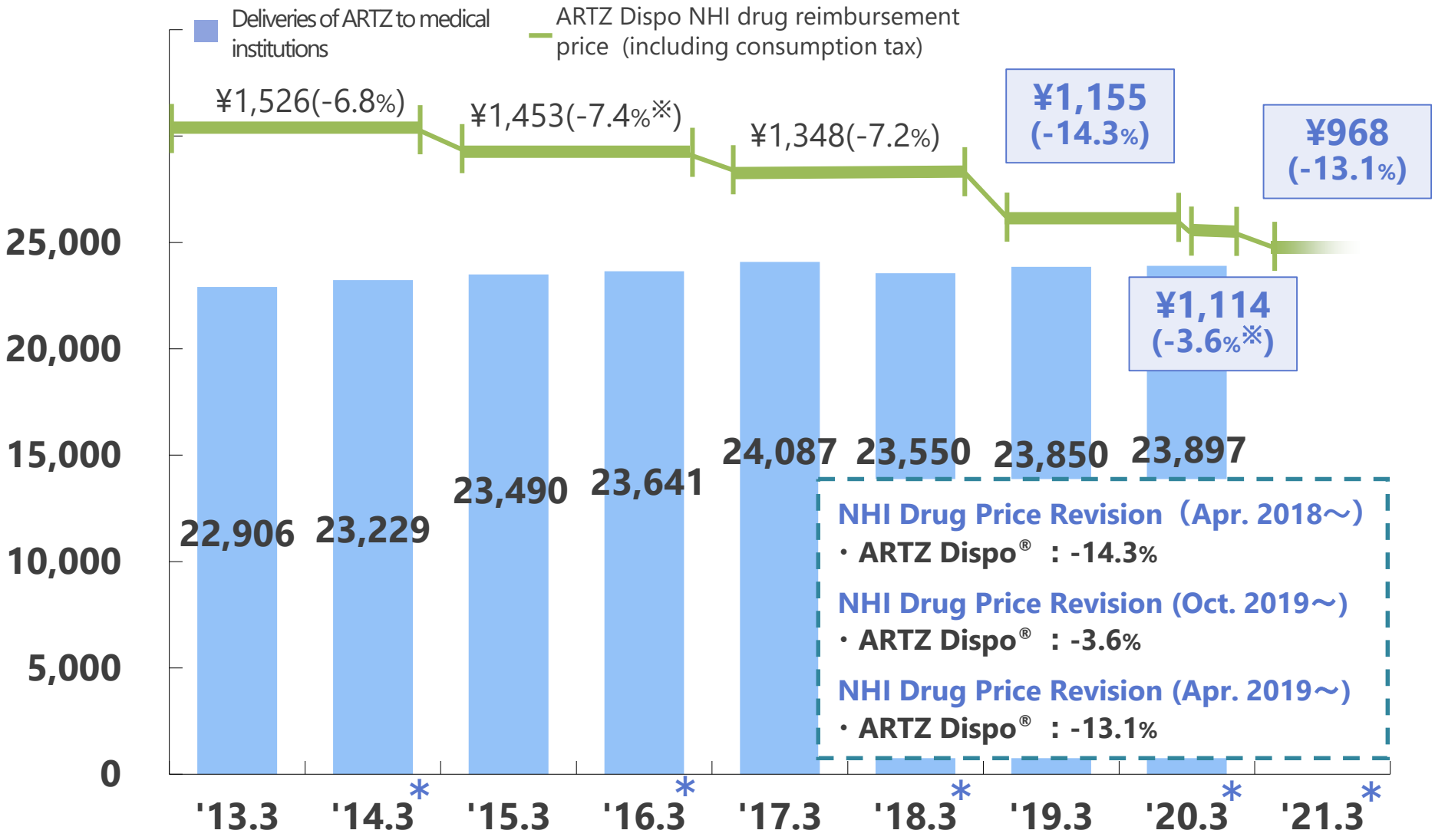
- Carrying out initiatives for strategic investments with prospects for future growth and synergy effects

	FY2015	FY2016	FY2017	FY2018	FY2019
Net Income per share	¥45.39	¥31.55	¥69.30	¥39.76	¥-192.15
Annual Total Dividend	¥26.00	¥31.00※	¥26.00	¥26.00	¥26.00
Dividend Payout Ratio	57.3%	98.3%	37.5%	65.4%	―

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

Appendix

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

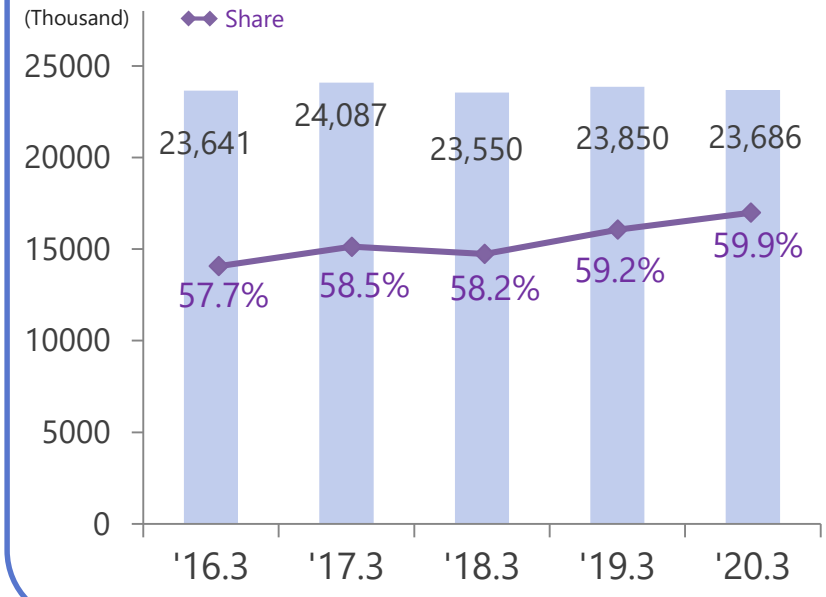
Trend in Deliveries of ARTZ / OPEGAN to Domestic Medical Institutions

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



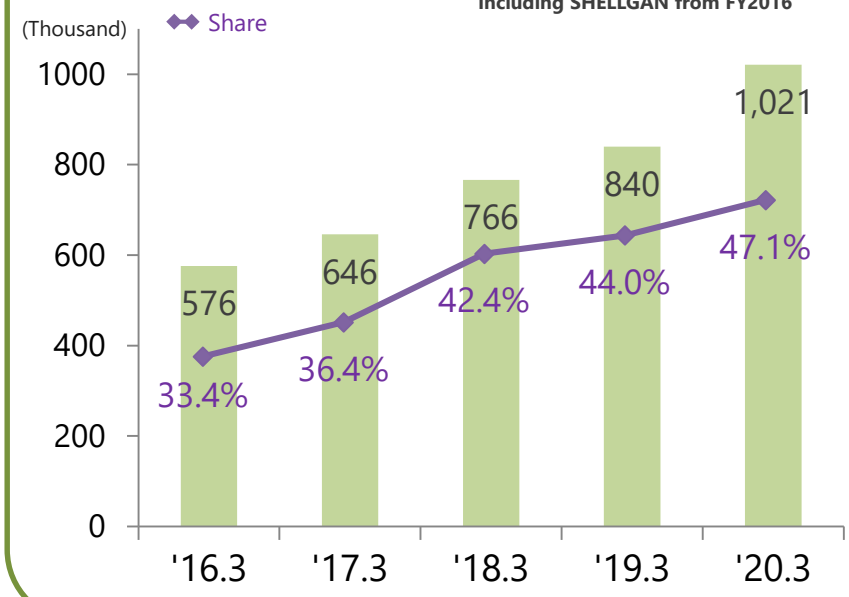
Ophthalmic viscoelastic devices

OPEGAN

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

Trend in unit deliveries to medical institutions

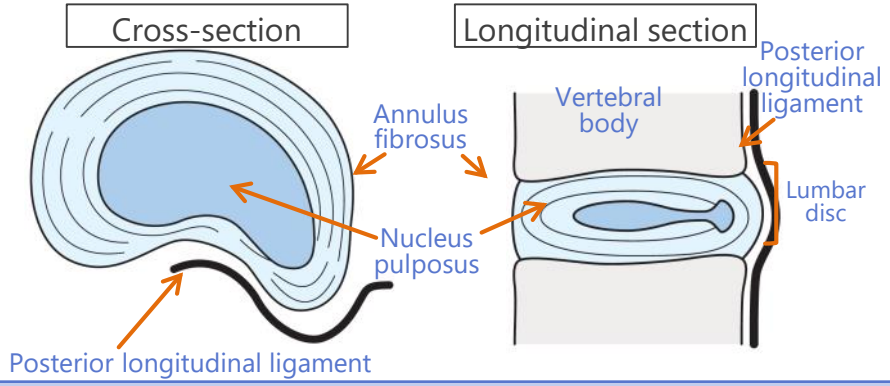
*Including SHELLGAN from FY2016



Four types of lumbar disc herniation

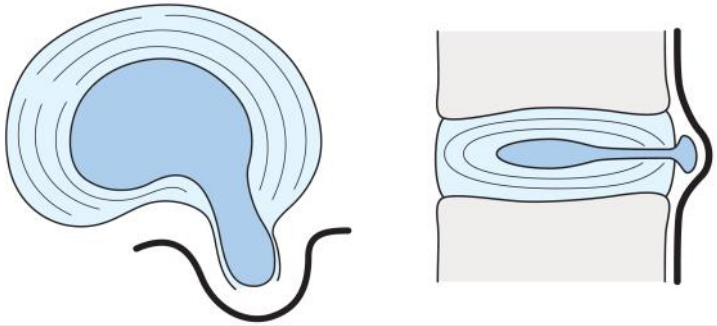
1. Protrusion

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



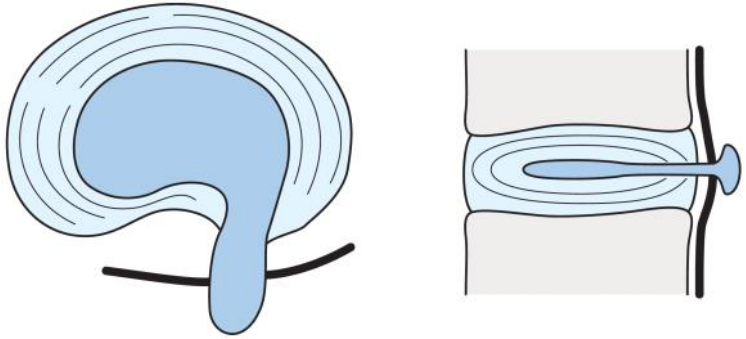
2. Subligamentous extrusion

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



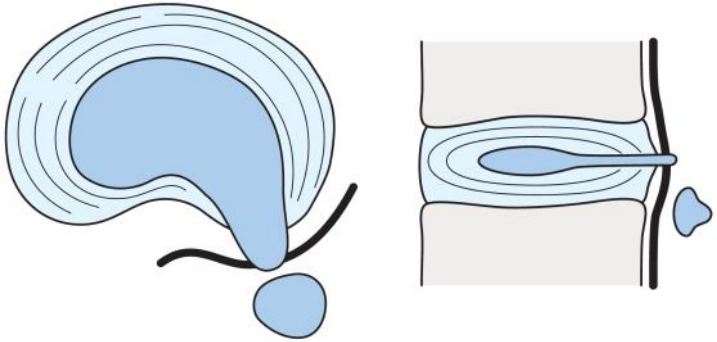
3. Transligamentous extrusion

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.

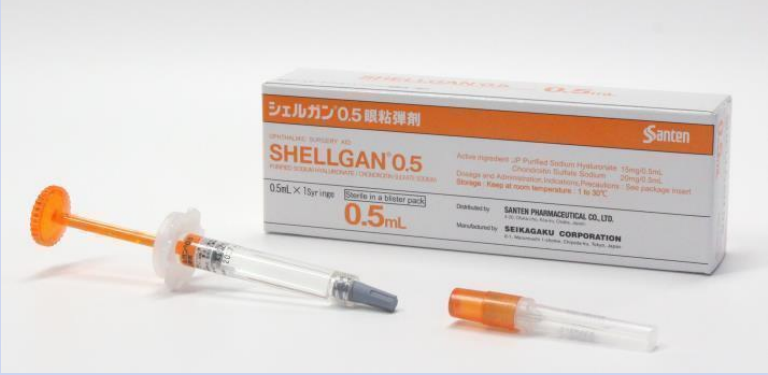
*PMDA: Pharmaceuticals and Medical Devices Agency

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

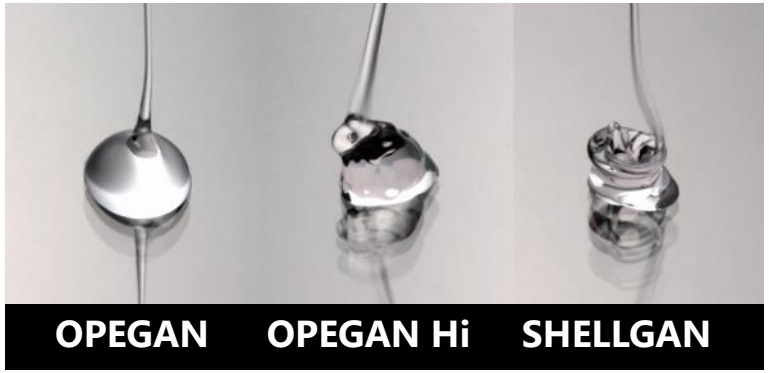
精製ヒアルロン酸ナトリウム/コンドロイチン硫酸エステルナトリウム



■ 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.

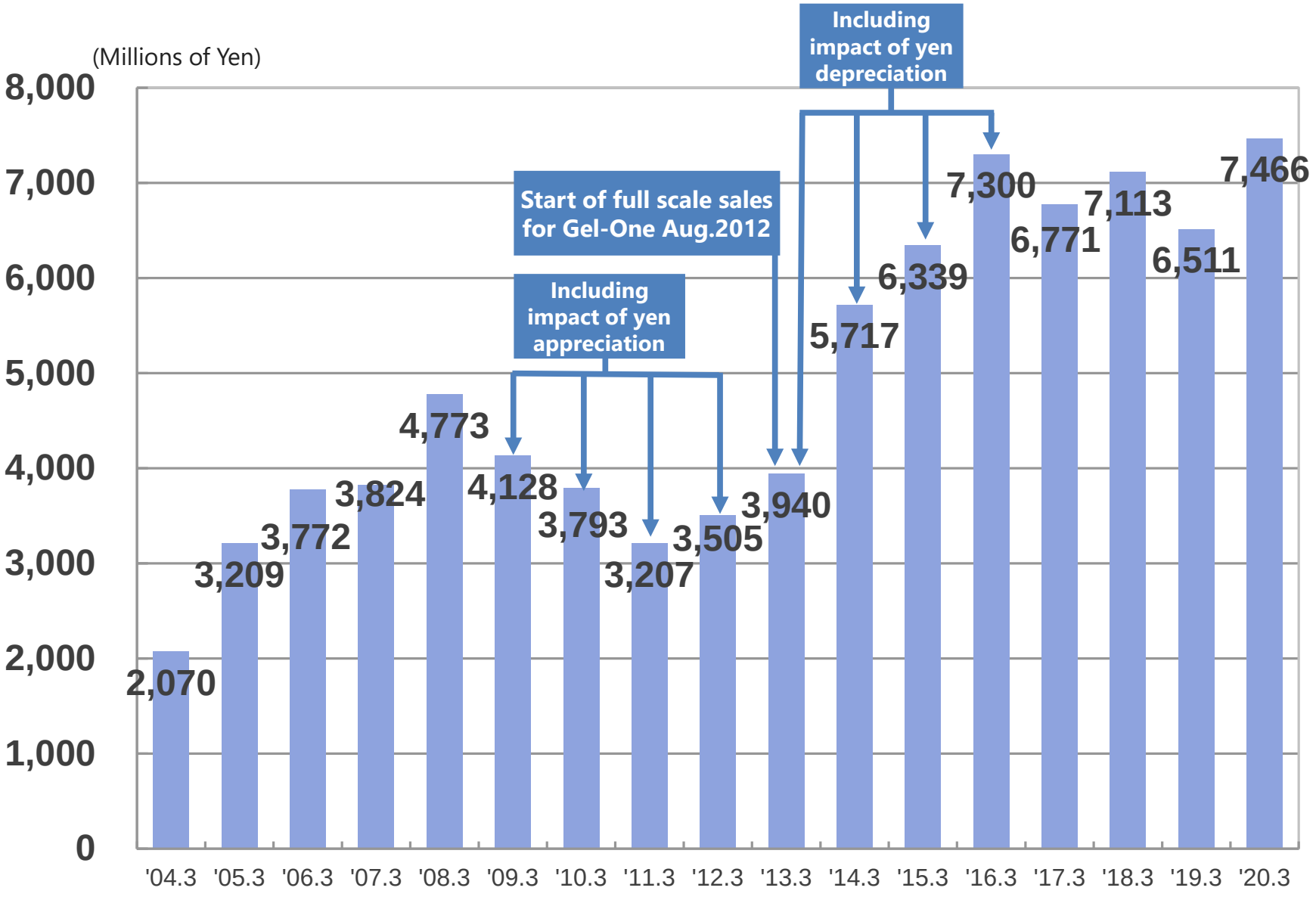
five-injection product
SUPARTZ FX

- 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

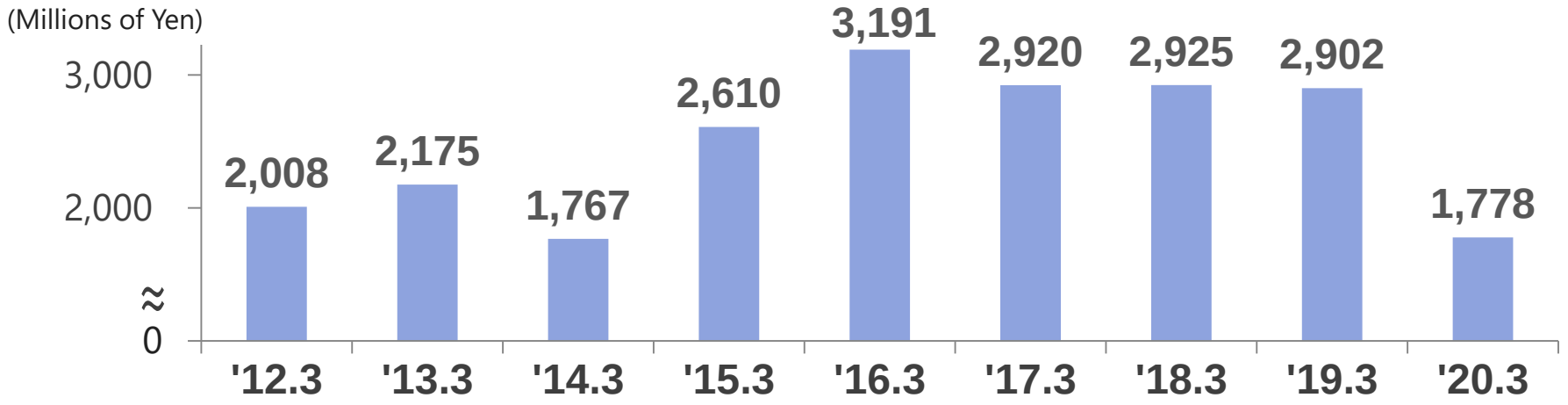
PYROCHROME®

Exterior of the ACC offices

Trends in Depreciation & Capital Investments

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

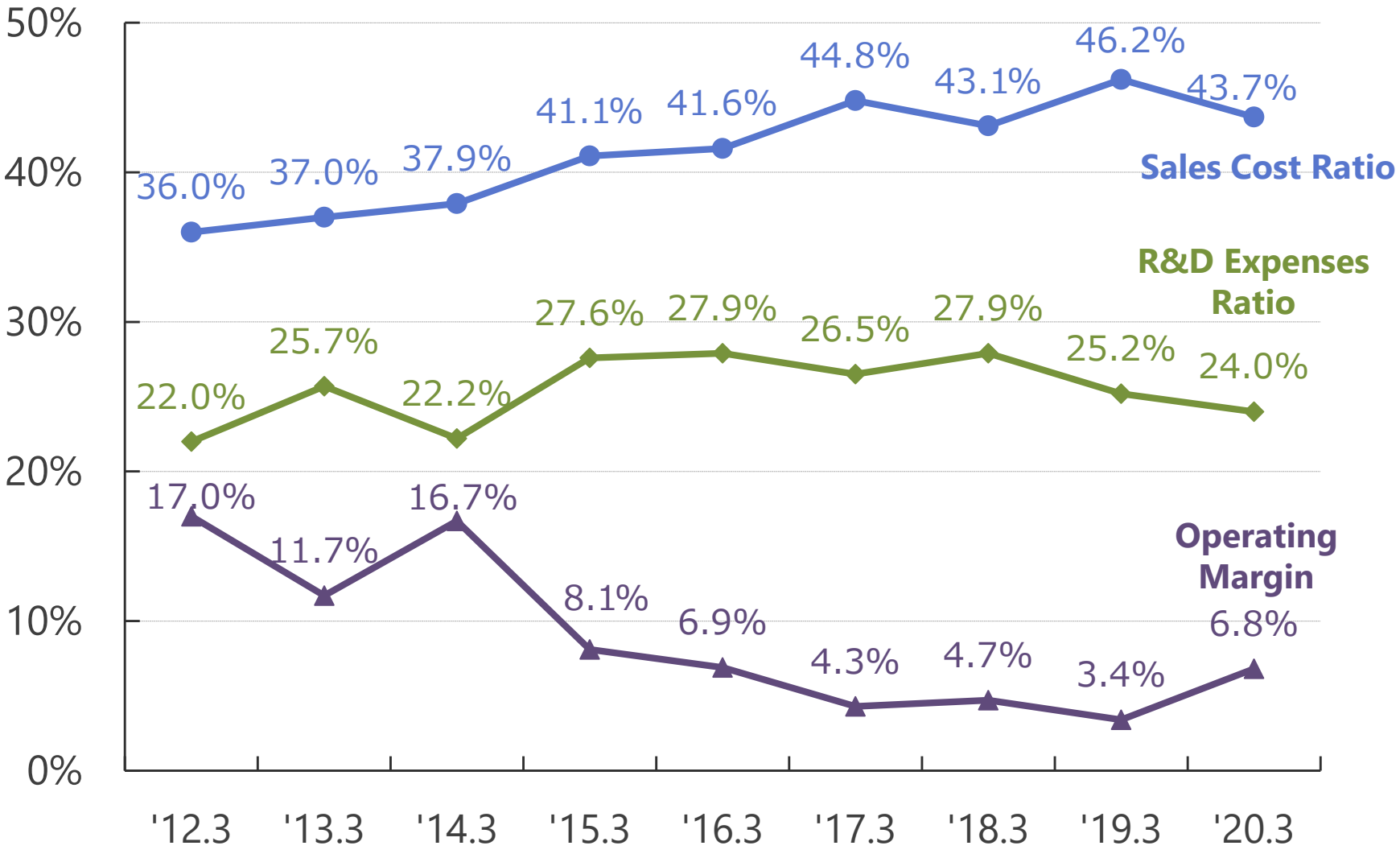
■ Trend in Depreciation



■ Trend in Capital Investments (Millions of Yen)

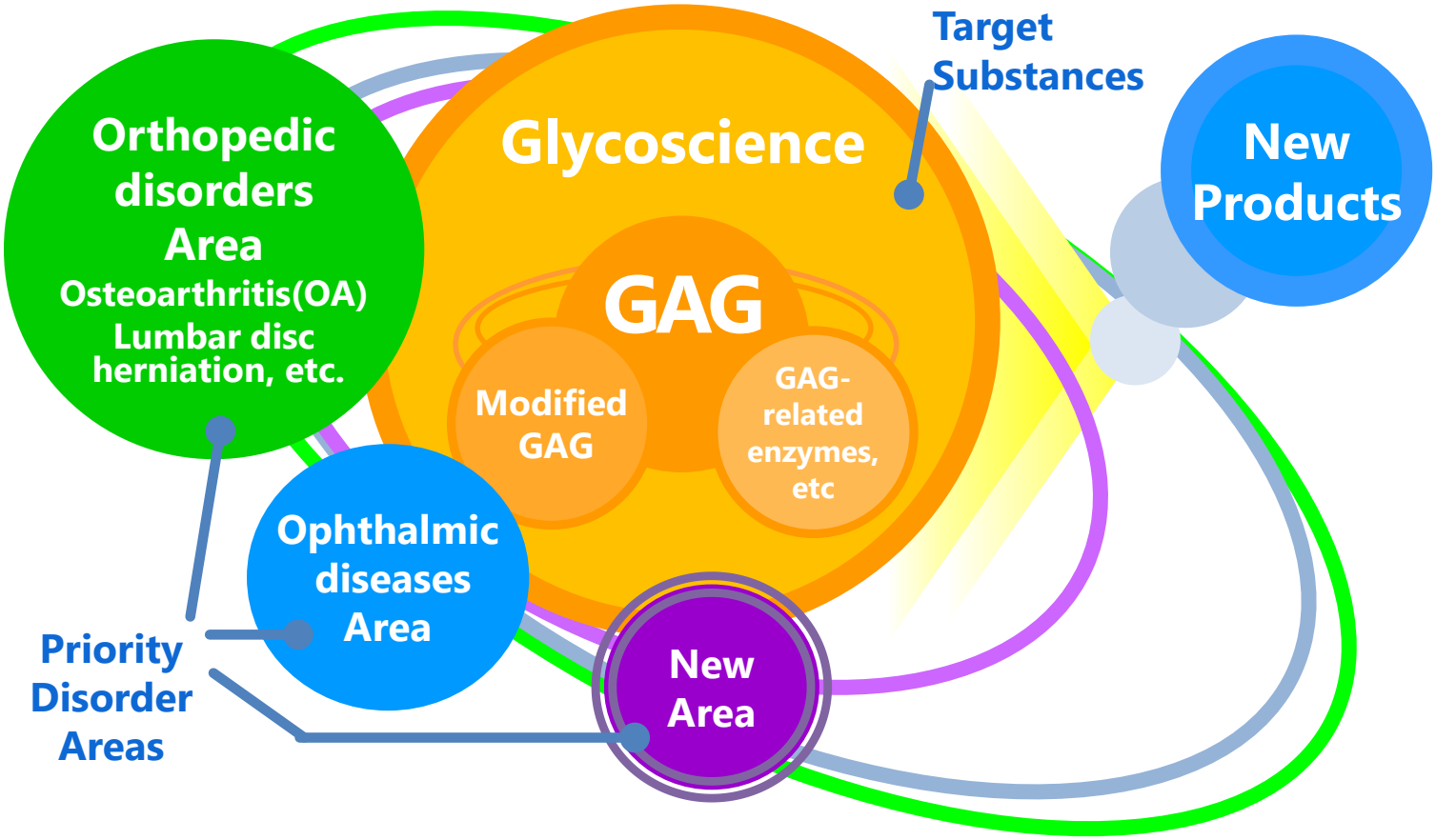
'12.3	'13.3	'14.3	'15.3	'16.3	'17.3	'18.3	'19.3	'20.3
5,718	9,164	7,222	2,095	1,975	1,173	1,591	1,310	2,109

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)

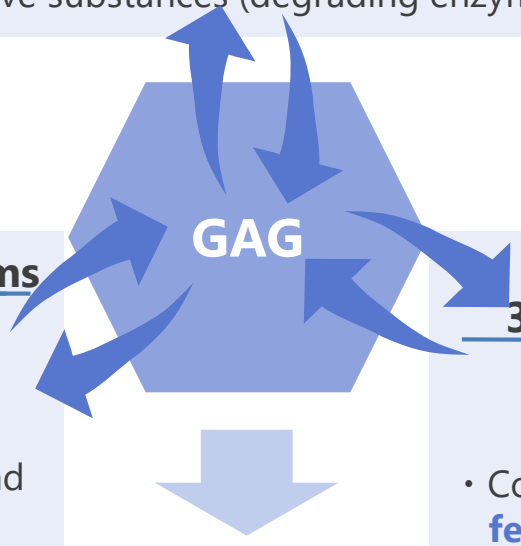
Strengthening and Making Use of The Company's Own GAG-related Core Technology

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

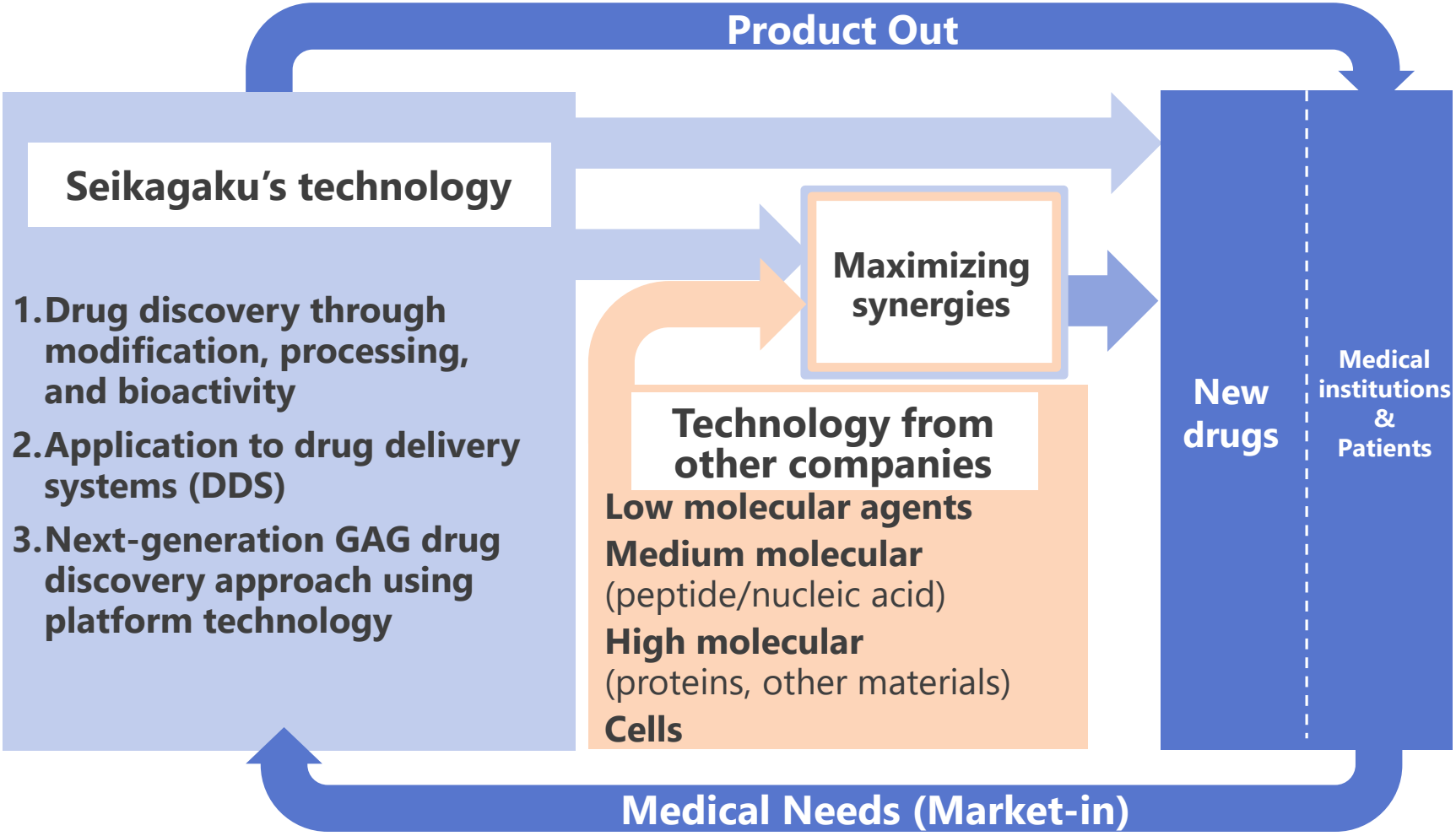
3. Next-generation GAG drug discovery approach using platform technology

- 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

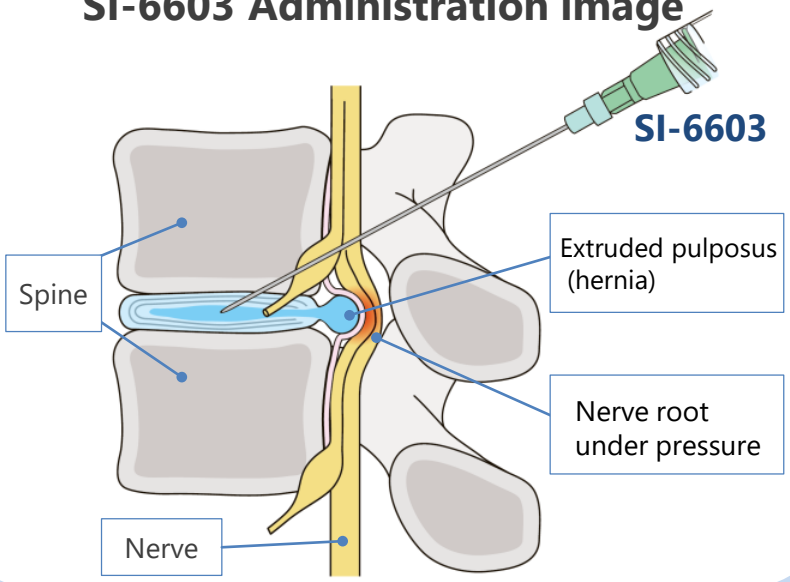
Speeding up and augmenting the number of projects through a drug discovery approach using Open Innovation



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.

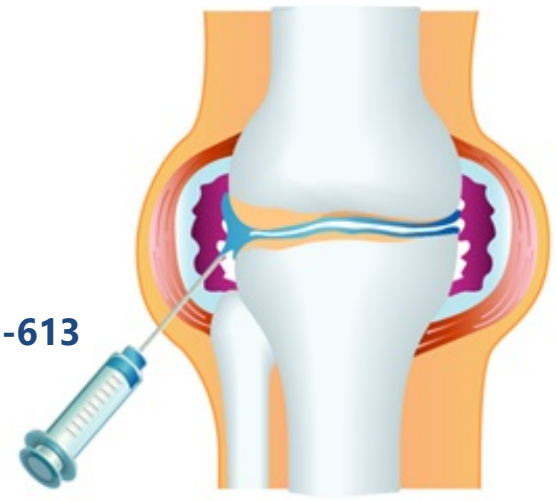
② There is possibility that some factors such as complications biased assessment of leg pain

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

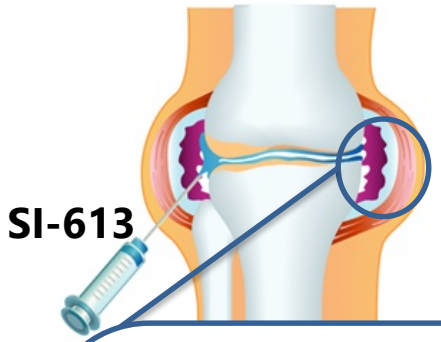
▶Hyaluronic acid and diclofenac (an anti-inflammatory agent) are chemically bound by the drug deriverly system
SI-613 is designed for sustained release * of diclofenac
Prompt and sustained relief of pain and inflammation

▶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

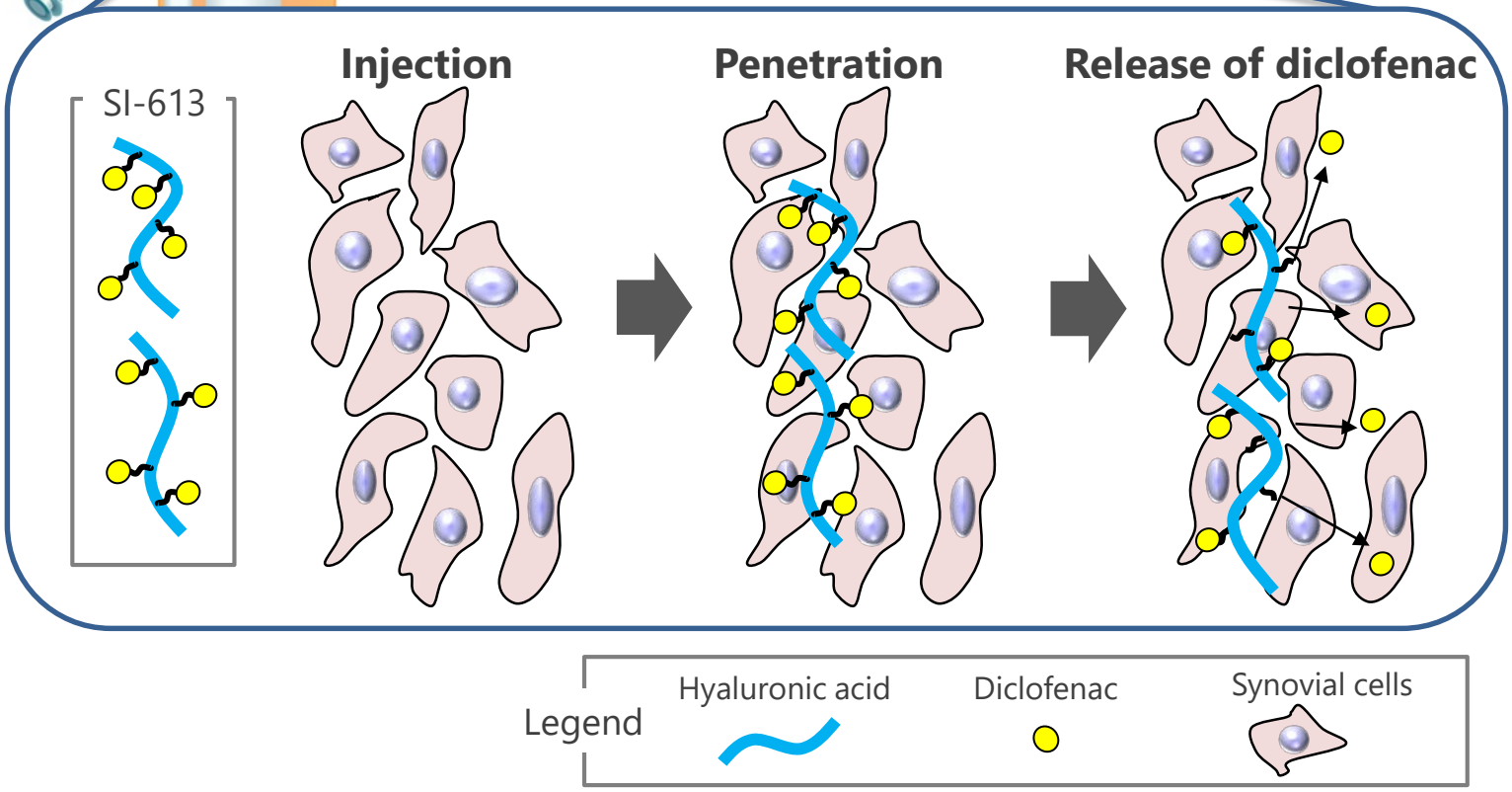
* Sustained release: Gradual release of active ingredients to achieve a sustained therapeutic effect

<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

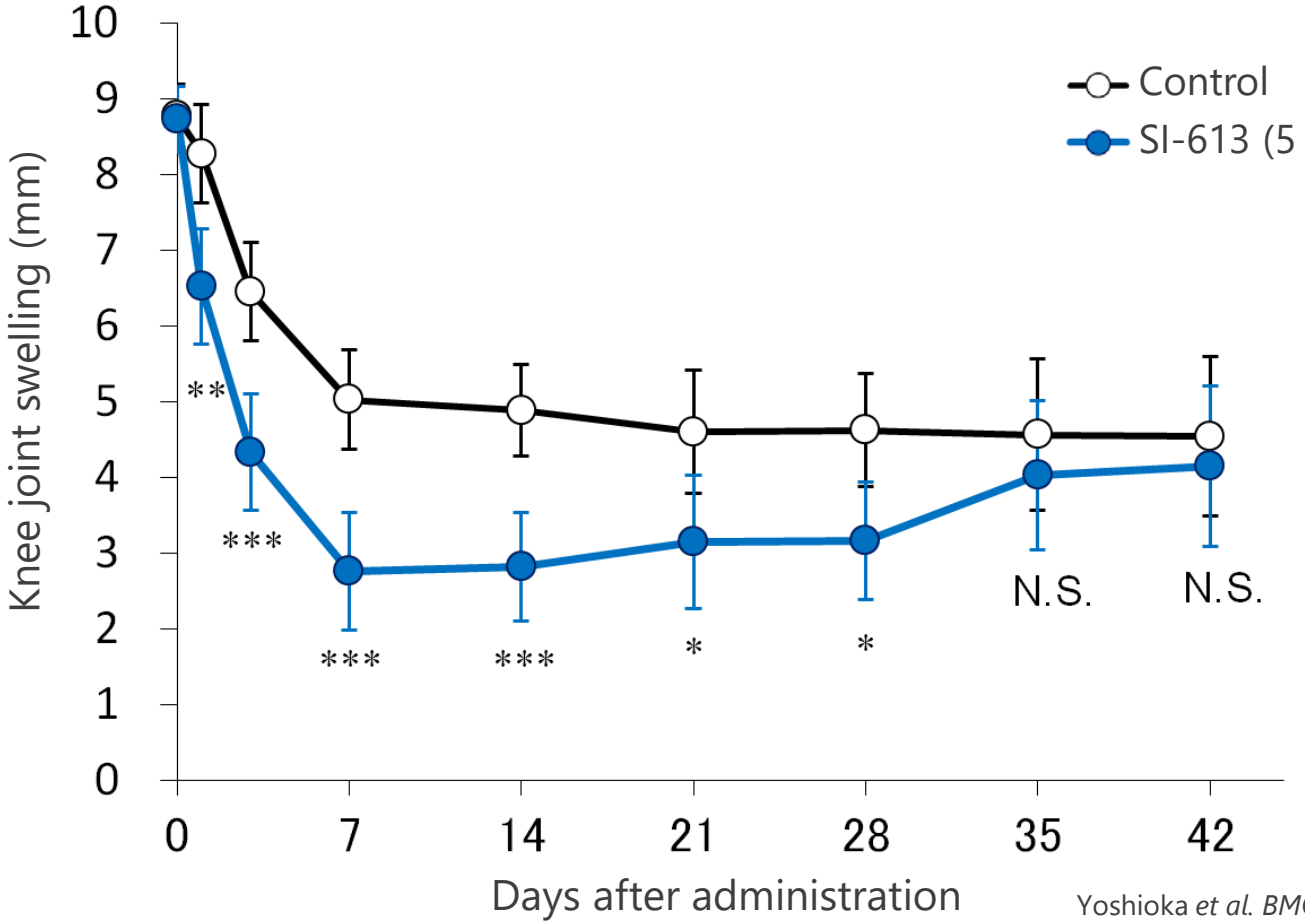


SI-613 (substance name: hyaluronic acid-diclofenac conjugate) is thought to penetrate the synovial membrane (connective tissue within the articular capsule) and gradually release diclofenac



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

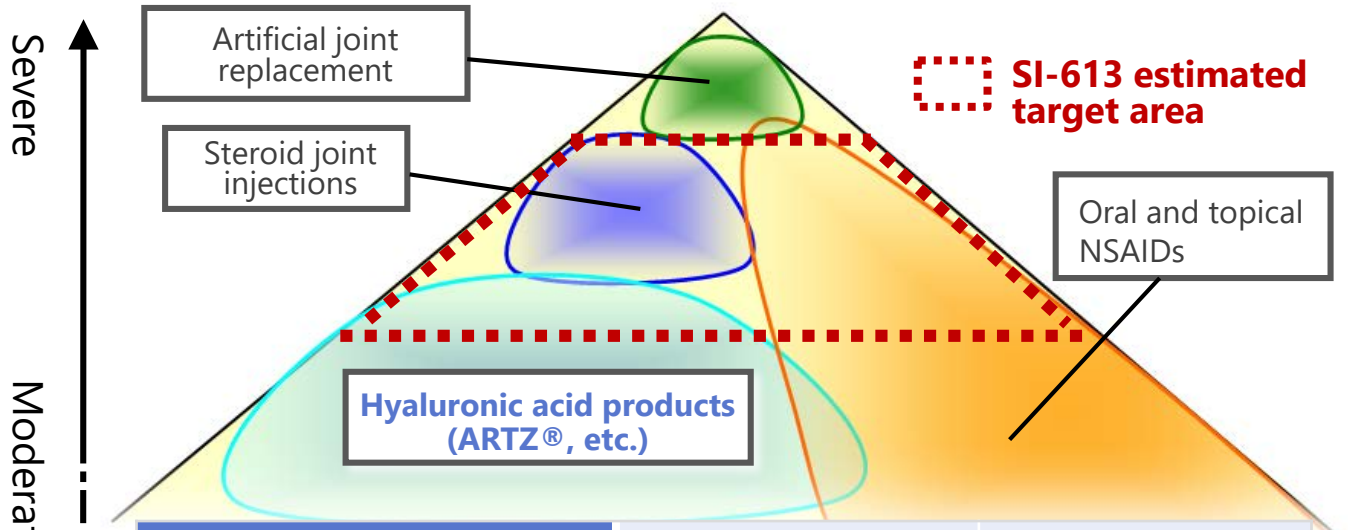


Mean±S.E. (n=20)
*** P<0.001, ** P<0.01, * P<0.05
N.S.(not significant) :
Student's *t*-test with
Holm's correction (vs control)

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

SI-613 Estimated Target Patients

Quickly fostering approval and launching as a new core product

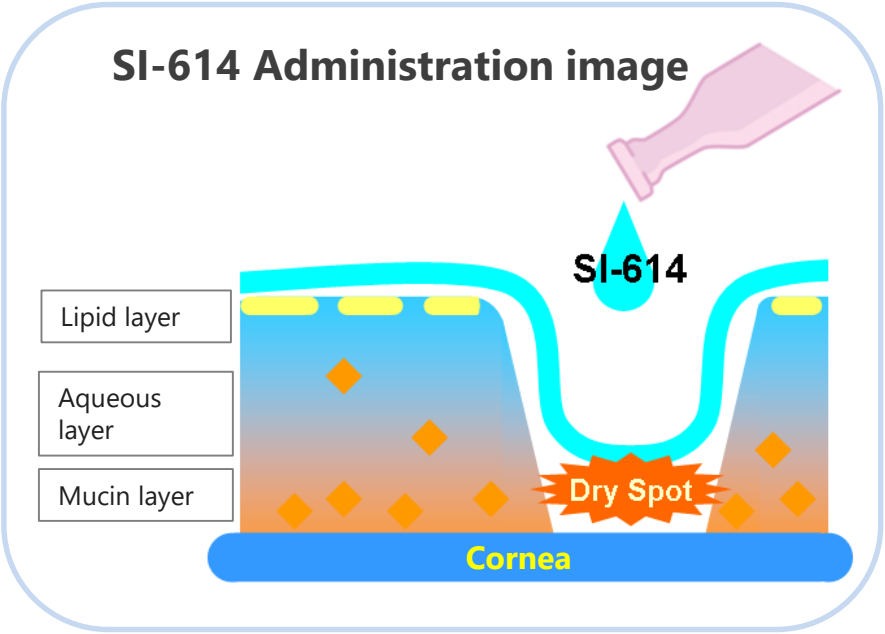


Target market size in Japan ＊Including applications outside the knee		
	Oral NSAIDs	¥ 83 billion
	Topical NSAIDs	¥144 billion
	HA injections	¥41 billion
	Steroid injections	¥11 billion

*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

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-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.

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	—
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%

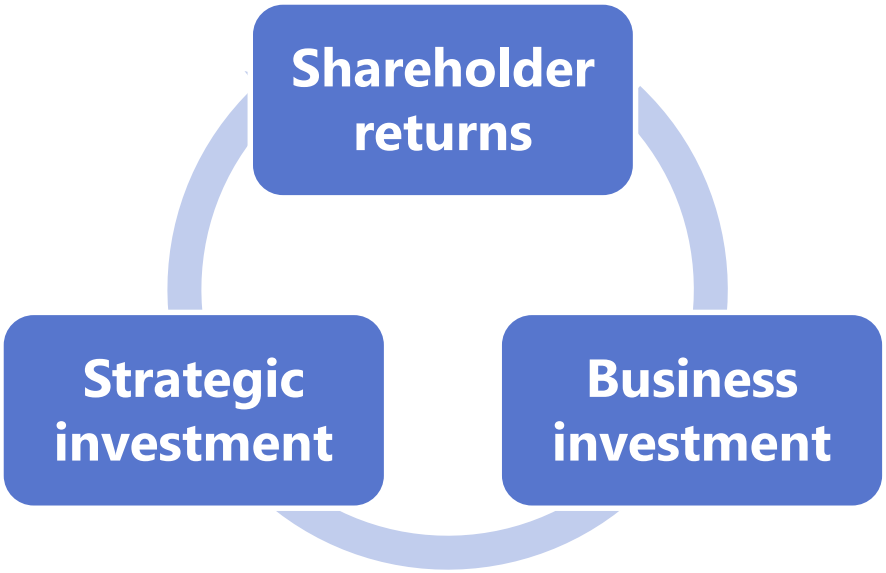
≪ Assumptions≫

- 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)

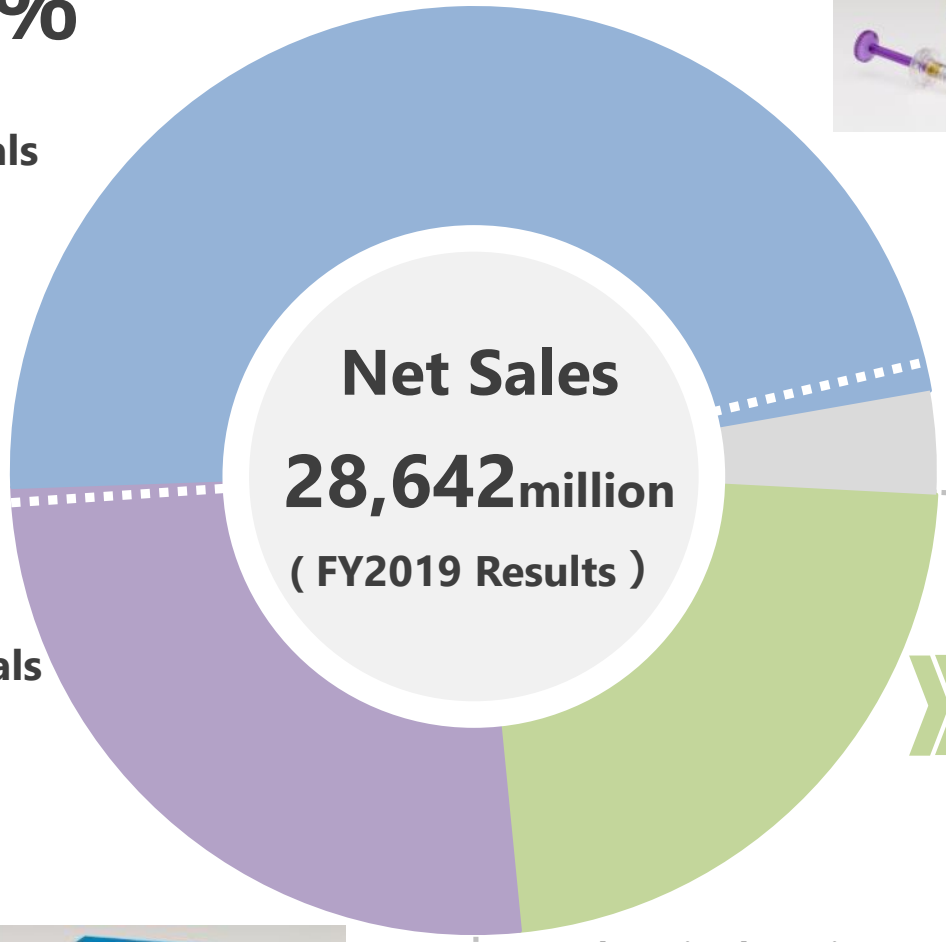
Our Business Segment

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.

https://www.ehiza.jp/

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