Exploring the Innovative Promise of Glycoscience

Financial Results for the 1st Quarter of Fiscal Year 2022

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.

Overview for 1Q of Fiscal Year 2022

(百万円)	1Q FY2022 Results	Year-on-Year	
		Change	% of Change
Net sales	**8,307**	**-3,476**	**-29.5%**
Operating Income	**1,126**	**-3,320**	**-74.7%**
Ordinary Income	**1,714**	**-2,898**	**-62.8%**
Net Income	**1,493**	**-2,159**	**-59.1%**
R&D Expenses (excluding royalty income)	**1,687** (20.3%)	**-248** (-3.2pt)	**-12.8%**
Average Exchange Rate (1US$)	¥129.57	¥+20.08	

	1Q FY2022 Results	1Q FY2021 Results
Net Income per Share	**¥26.62**	¥64.73

Net sales by Business Segment (1Q of FY2022)

(Millions of Yen)	1Q FY2022 Results	Year-on-Year	% of Change
Net sales	8,307	-3,476	-29.5%
Pharmaceuticals	5,488	-4,219	-43.5%
Domestic Pharmaceuticals	2,965	-881	-22.9%
Overseas Pharmaceuticals	1,788	+198	+12.5%
Bulk Products /CDMO	732	+12	+1.7%
Royalty Income	1	-3,548	-100.0%
LAL Business	2,819	+742	+35.7%
(Overseas sales)	4,766	+872	+22.4%

＊ Foreign exchange impact on overall net sales ： approx. +450million yen

Domestic Pharmaceuticals

▶ ARTZ (Joint-function improving agent)

- Market recovering from COVID-19 impact (+0.6%)
- Recovery in deliveries to medical institutions and increased switching from competing products (+2.6%)
- Market share expands (+1.2pt)
- Shipment volumes rise as a result of shipment schedule adjustment, but Company sales fall due to NHI drug price reduction

▶ JOYCLU (Joint-function improving agent)

- May 2021 start of sales
- Deliveries to medical institutions increase due to year-on-year shortening of selling period
- Steep decline in Company sales attributable to concentration of shipments in FY2021 1Q for the launch
- Information provision efforts to ensure appropriate use

Safety Information on Joint Function Improving Agent JOYCLU

Blue Letter (rapid safety information) issued June 1
Prompt provision of information to alert healthcare professionals
Initiation of clinical research to identify the cause

Dear Healthcare Professionals Letter of Rapid Safety Communication (Blue Letter) issued on June 1 in response to multiple reports of anaphylaxis occurring in patients following administration of JOYCLU

- To ensure patient safety by promptly alerting healthcare professionals of the situation to enable the provision of appropriate treatment and measures
- Addition of a WARNING section to the drug package insert and revision of the IMPORTANT PRECAUTIONS section
- Leaflet created to alert patients and their families to the risk of side effects

Continued gathering of safety information and provision of safety-related information in collaboration with sales partner Ono Pharmaceutical.
In April 2022, initiation of physician-led clinical research to identify the cause.

Information included in the package insert at the time of NDA approval
- Important Side Effects: Shock, anaphylaxis (0.4%)
- Contraindications: Patients with a previous history of hypersensitivity to diclofenac sodium and sodium hyaluronate (the ingredients of JOYCLU)

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Domestic Pharmaceuticals

▶ OPEGAN series (Ophthalmic viscoelastic devices)

- Market expands amidst return to pre-pandemic growth as COVID-19 impact subsides (+12.0%)
- Increased deliveries to medical institutions amidst market expansion (+11.3%)
- Share at prior-year level (-0.3pt)
- Company sales fall as sales partners adjust inventories and NHI drug price reductions

▶ MucoUp (Submucosal injection agent for endoscopic surgery)

- Company sales increase from low prior-year shipment level

▶ HERNICORE (Treatment for lumbar disc herniation)

- Deliveries to medical institutions at prior-year level
- Company sales increase due to impact from shipment timing

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Overseas Pharmaceuticals

*Foreign exchange impact on Overseas Pharmaceuticals: approx. +150 million yen

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

- A general market recovery from COVID-19
- Local sales volume down reflecting the market anticipation of a July 2022 health insurance system change related to price disclosure
- Company sales rise sharply on increased volumes due to shipment timing and yen depreciation

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

- Local sales volume at prior-year level
- Company sales increase due to yen depreciation

▶ ARTZ in China (Multiple injection)

- Local sales volume drops significantly due to lockdowns in major cities in response to the renewed spread of COVID-19
- Company sales: No 1Q shipments due to current inventories reflecting prior-year build-up accompanying changes in packaging materials
- Shipments scheduled to restart in August

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Bulk Products / CDMO

*Foreign exchange impact on Bulk Products/CDMO: approx. +50million yen

The Company's sales were at the prior-year level, CDMO sales at Dalton decline for pharmaceuticals, while sales of bulk products rise

Royalty Income

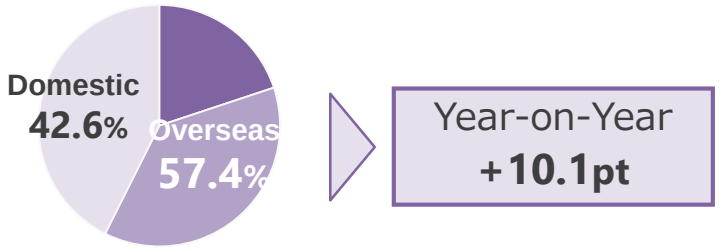
Substantial decline

LAL Business

*Foreign exchange impact on LAL Business: approx. +250million yen

In addition to a steady trend in domestic sales, sales up on growth in sales of ACC's reagents for Bacterial Endotoxin Testing (BET), contract services and Clinical Diagnostic (Fungitell) reagents

Overseas Sales Ratio (excluding royalty income)



Income for 1Q of FY2022 (Year-on-Year)

(Millions of Yen)	1Q FY2022 Results	Year-on-Year	% of Change
Net sales	8,307	-3,476	-29.5%
Cost of Sales (excluding royalty income)	3,622 (43.6%)	-93 (-1.5pt)	-2.5%
SGA expenses	3,558	-62	-1.7%
R&D Expenses (excluding royalty income)	1,687 (20.3%)	-248 (-3.2pt)	-12.8%
Operating Income (to Net sales ratio)	1,126 (13.6%)	-3,320 (-24.1pt)	-74.7%
Ordinary Income	1,714	-2,898	-62.8%
Net Income	1,493	-2,159	-59.1%
Depreciation	290	+65	+29.2%

Operating Income 1,126(-3,320)

Cost of sales ratio （-1.5pt）

- With NHI drug price reductions having an impact, ratio falls due to changes in sales mix

SGA Expenses （-62）

- Completion of subject enrollment for an additional U.S. clinical study of SI-6603 leads to lower R&D expenses （-248）

Ordinary Income 1,714 (-2,898)

Non-operating Income / Expenses （+421）

- Increase in foreign exchange gain（+415）

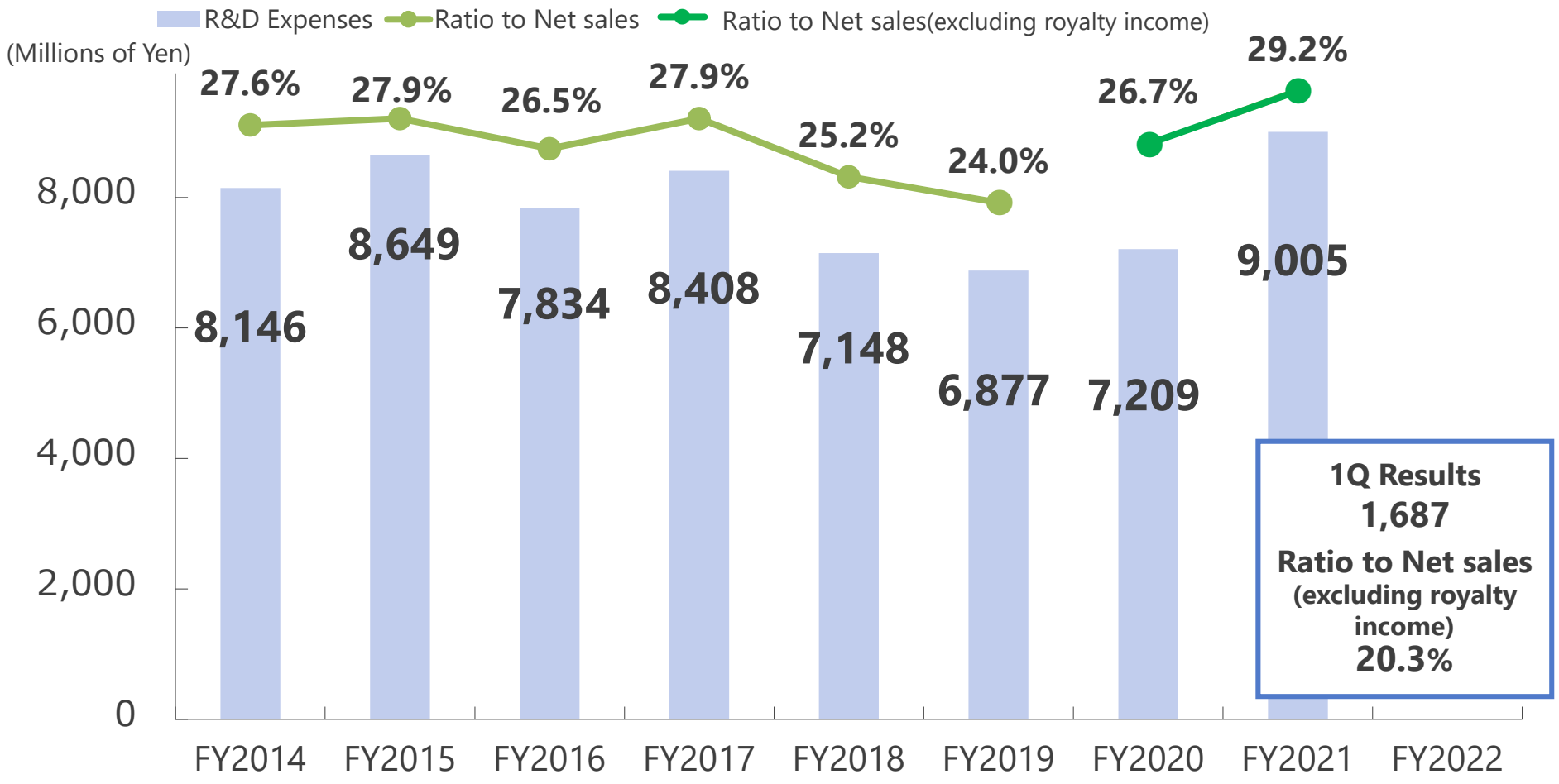
Ordinary Income 1,493 (-2,159)

Income Taxes （-739）

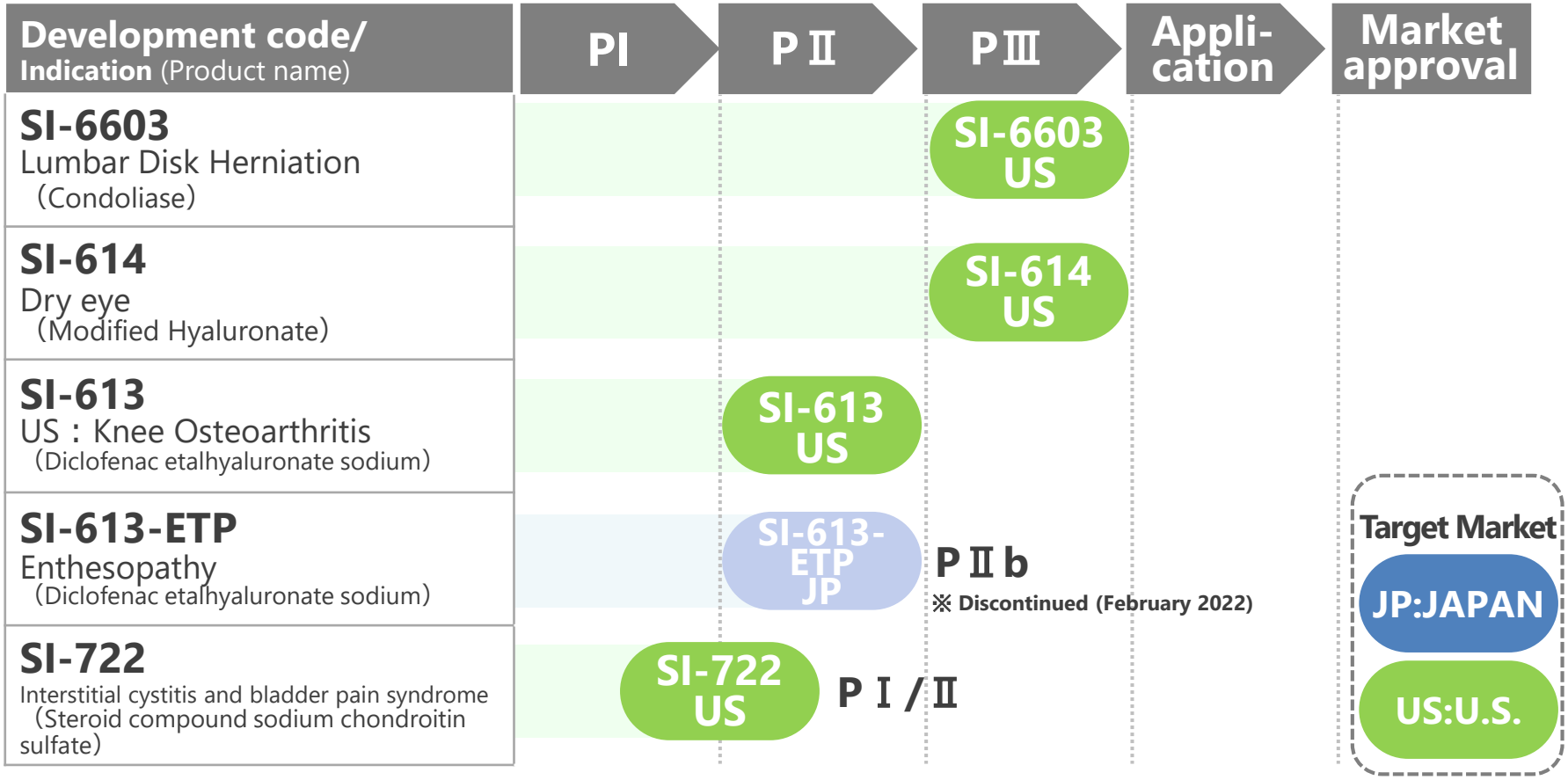
- Decline from high profits in previous fiscal year

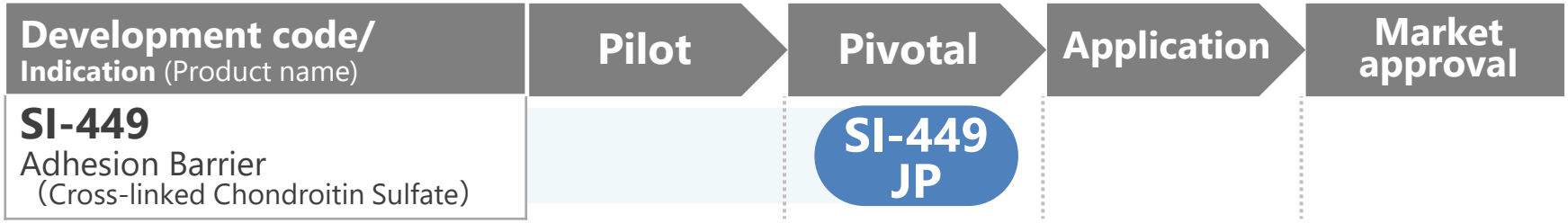
Trend in R&D Expenses

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



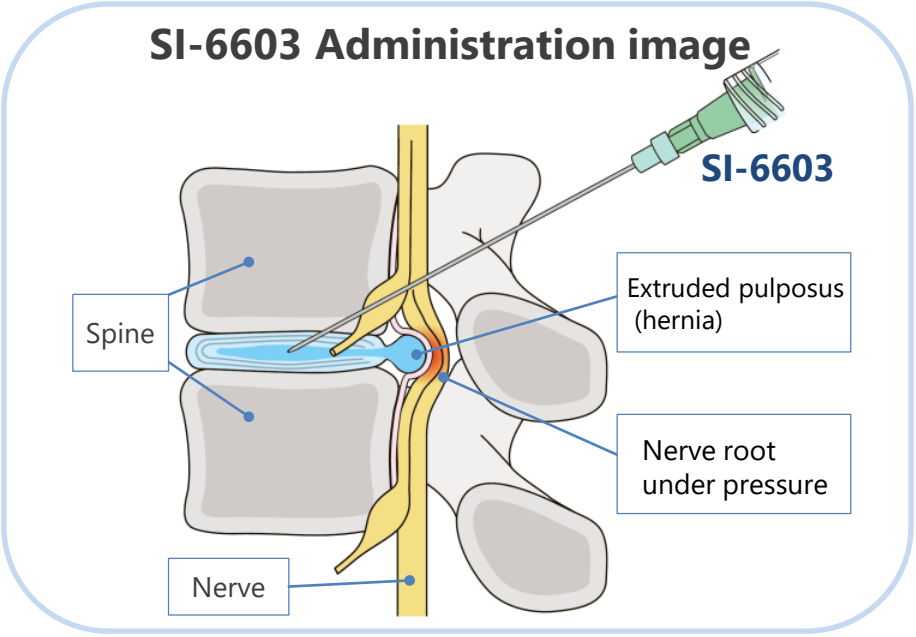
Pipeline List (Research and Development themes)





SI-6603 (Lumbar disc herniation)

Subject enrollment completed in March 2022
Move on to follow-up observation



Development status

▶ **U.S. Phase III** ：Starting February 2018
- **Subject enrollment complete in March 2022**

⇒ **Conduct a one-year follow-up observation**

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

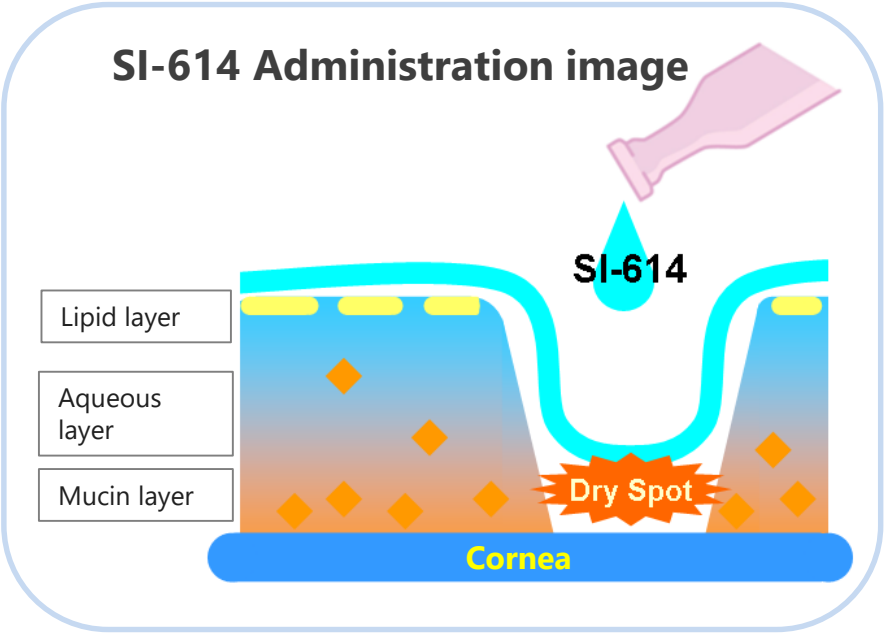
Indication ：Lumbar disc herniation

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-614 (Dry Eye)

PIII study in the U.S. initiated in May 2022
Evaluate efficacy and safety



Development status

▶ **U.S. : P III**

Initiated May 2022

- **Clinically beneficial effects confirmed in PII/PIII clinical studies**
- **Evaluation of efficacy and safety**

Expected 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 : 14 million (Seikagaku estimates)

SI-613 (Osteoarthritis/Enthesopathy)

Development of SI-613-ETP discontinued
Prioritize identification of cause of JOYCLU side effects

SI-613 (osteoarthritis of the knee) U.S. /China/South Korea

▶ Proceeding with preparation of a clinical development plan

SI-613 (Enthesopathy) Japan

▶ **February 2022: Development discontinued**

⇒ Failure of the PII clinical study to meet its primary efficacy evaluation, and to prioritize identification of the cause of shock or anaphylaxis occurring in patients following administration of JOYCLU

<SI-613 summary>

Dev. code ：SI-613　　Generic name ：Diclofenac etalhyaluronate sodium

Indication ：Osteoarthritis/Enthesopathy

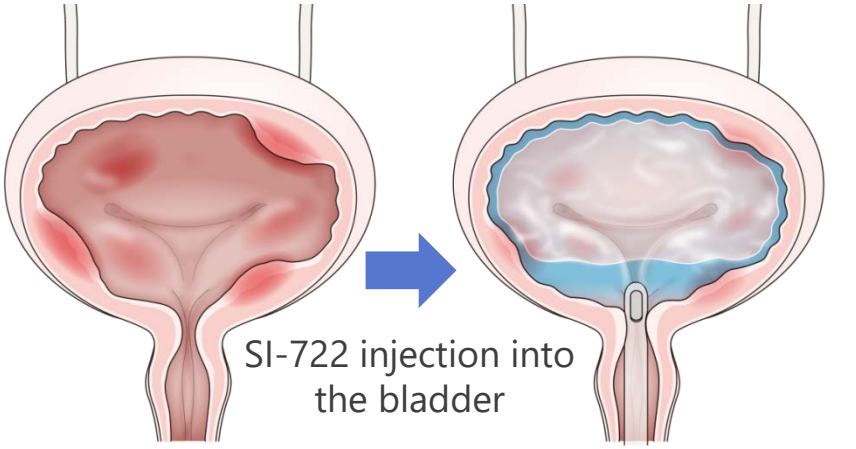
Method of use ：Injection into joint cavity

Estimated patients： 24 million (U.S.) / 47 million (China)
3.2 million (South Korea) (Seikagaku estimates)

SI-722 (Interstitial cystitis and bladder pain syndrome)

Subject enrollment for PI/PII studies in the U.S. completed
Analysis of study results to proceed

SI-722 Administration image



Development status

▶ **U.S. Phase I/II** : Starting November 2019
- Subject enrollment complete in January 2021

⇒**Tolerability confirmed (a primary objective)**
Will consider the next-phase study

Expected Features

▶ Designed for sustained release by bonding steroids to chondroitin sulfate

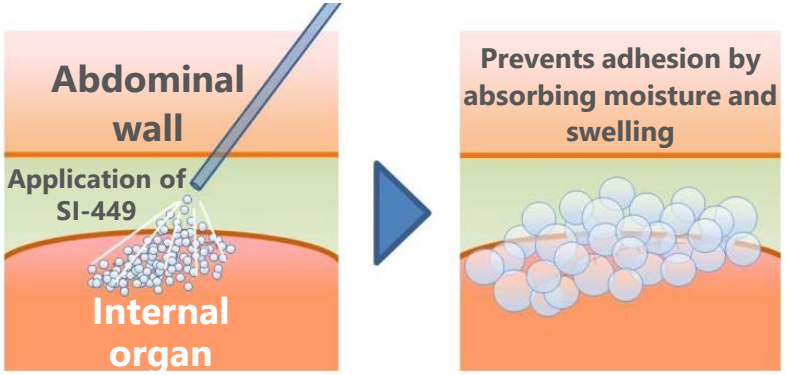
▶ Anti-inflammatory effects of steroids under sustained release should provide sustainable relief of frequent urination and bladder pain

<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)

Commenced pilot study in field of gynecology in November 2021
Aiming to expand range of applications

SI-449 Administration image



Development status

- **Japan pivotal study (field of gastroenterological surgery)**
  Starting May 2020
  - Evaluated for effectiveness, safety, and usability

  ⇒Subject enrollment is steadily proceeding thanks to the effectiveness of measures, despite delay due to the spread of COVID-19 infection
- **Japan pilot study (field of gynecology)**
  Starting November 2021
  - Confirming operability and safety
  - Aiming to expand range of applications

  ⇒Subject enrollment complete in May 2022
- Proceed with development with a view to global development; Start of U.S. pilot study under review

Expected 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: ¥14 billion, Global: ¥100 billion (Seikagaku estimates)

Dividend of Surplus and Acquisition of Treasury

Treasury Shares Acquired
Dividend Policy Review to Coincide with Mid-Term Management Plan Formulation

FY2022

Annual dividend：¥22 per share, including the interim dividend of ¥11 per share

	FY2018	FY2019	FY2020	FY2021	FY2022 (Forecast)
Net Income per share	¥39.76	¥-192.15	¥75.54	¥66.32	—
Annual Total Dividend	¥26.00	¥26.00	¥24.00※1	¥30.00※2	¥22.00
Dividend Payout Ratio	65.4%	—	31.8%	45.2%	—

※1 including a JOYCUL approval commemorative dividend ¥4
※2 including a JOYCUL launch special dividend ¥10

Acquisition of Treasury

Total number of shares to be acquired：2,000,000shares (maximum)
Total amount of acquisition cost：¥1,500 million (maximum)
Acquisition period：May 16, 2022 to November 30, 2022

【Total number and yen amount of own shares repurchased from May 16, 2022 through July 31, 2022】
Total number of own shares repurchased：685,900 shares
Total repurchase amount：560,497,300 yen

Appendix

Forecasts for Fiscal 2022

Fiscal 2022 financial forecasts

It is difficult at present to prepare reasonable forecasts of consolidated financial results for fiscal 2022 because it is necessary to assess the progress of efforts to identify the cause of shock or anaphylaxis occurring in patients following administration of the joint function improvement agent JOYCLU. Accordingly, the Company will refrain from announcing earnings forecasts at this time.

Once it becomes possible to prepare reasonable forecasts, the Company will promptly announce them.

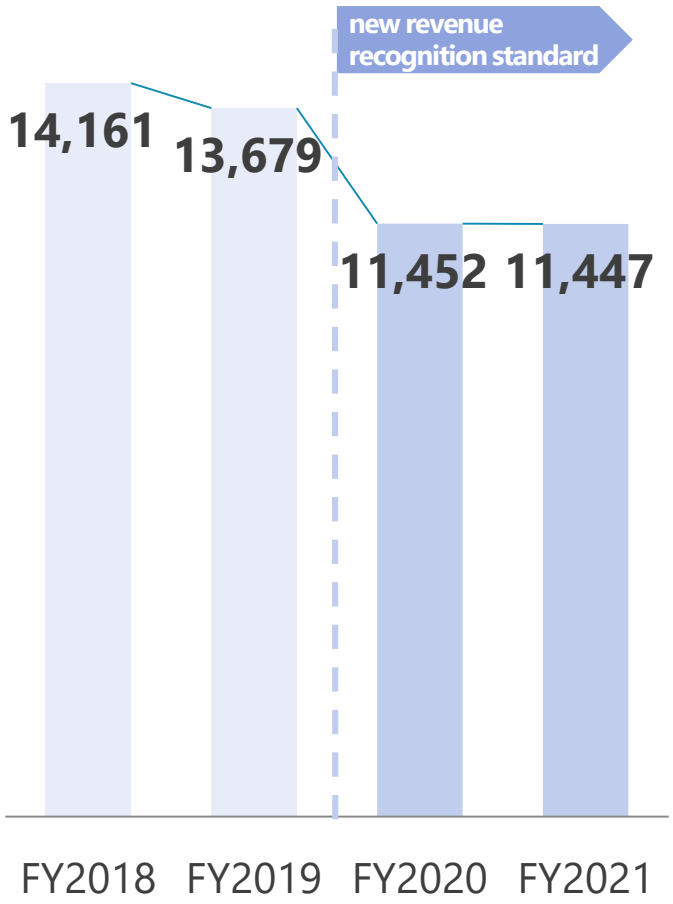
Current Assumptions

- Drug price reductions (implemented April 2022) Approx.
  : -11% (Weighted average for domestic pharmaceuticals as a whole)
  ARTZ: -12.6%　OPEGAN: -7%
- FY2021 overseas sales ratio: Approx. 56% (denominated mainly in U.S. dollars)
  Financial results will be affected by any sharp yen appreciation or depreciation from the FY2021 average exchange rate (¥112.4 to US$1)
- Royalties: decrease expected due to non-recurrence of a prior-year one-time increase
- R&D expenses: decrease expected due to completion of subject enrollment for an additional clinical study in the U.S. for SI-6603, a treatment for lumbar disc herniation
- COVID-19 infection impact at the same level as in FY2021

Domestic Pharmaceuticals 1/2 (FY2021Results Year-on-Year)

Domestic Pharmaceuticals Sales trend

(Millions of Yen)



FY2021 Results
-0.0% (sales basis)

Sales at the prior-year level, with recovery from the impact of COVID-19 and the launch of JOYCLU compensating for the impact of NHI price reductions

Joint-function improving agent (Unit deliveries to medical institutions)

Market (+1.0%)

- Trend toward recovery from the impact of COVID-19

ARTZ (+3.0%)

FY2021 Results

- Volume and market share increases due to market recovery and the continued impact of measures to acquire new user facilities (62.4% / +1.2pt)

FY2022 Assumptions

- Forecasting sales at the prior-year level due to efforts to maintain market share

JOYCLU

FY2021 Results

- Negative sales of products with approaching ship-by dates recorded in 3Q in connection with issuance of the Blue Letter

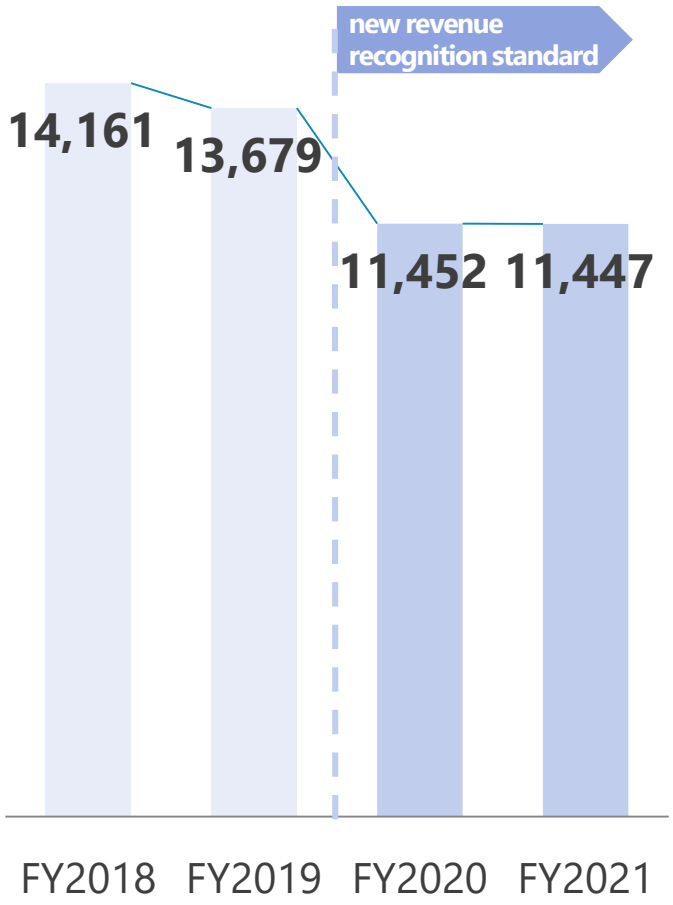
FY2022 Assumptions

- Information provision efforts to ensure appropriate use

Domestic Pharmaceuticals 2/2 (FY2021Results Year-on-Year)

Domestic Pharmaceuticals Sales trend

(Millions of Yen)



FY2021 Results

-0.0% (sales basis)

Sales at the prior-year level, with recovery from the impact of COVID-19 and the launch of JOYCLU compensating for the impact of NHI price reductions

Ophthalmic viscoelastic devices (Unit deliveries to medical institutions)

Market (+7.0%)

- Trend toward recovery from the impact of COVID-19

OPEGAN (+3.5%)

FY2021 Results

- Volume increase accompanying market recovery
- Market share contraction following a prior-year volume increase due to shipment adjustments for competing products (51.9% / -1.8pt)

FY2022 Assumptions

- Sales at prior-year level due to retention of newly acquired accounts

Treatment for lumbar disc herniation (Unit deliveries to medical institutions)

HERNICORE

FY2021 Results

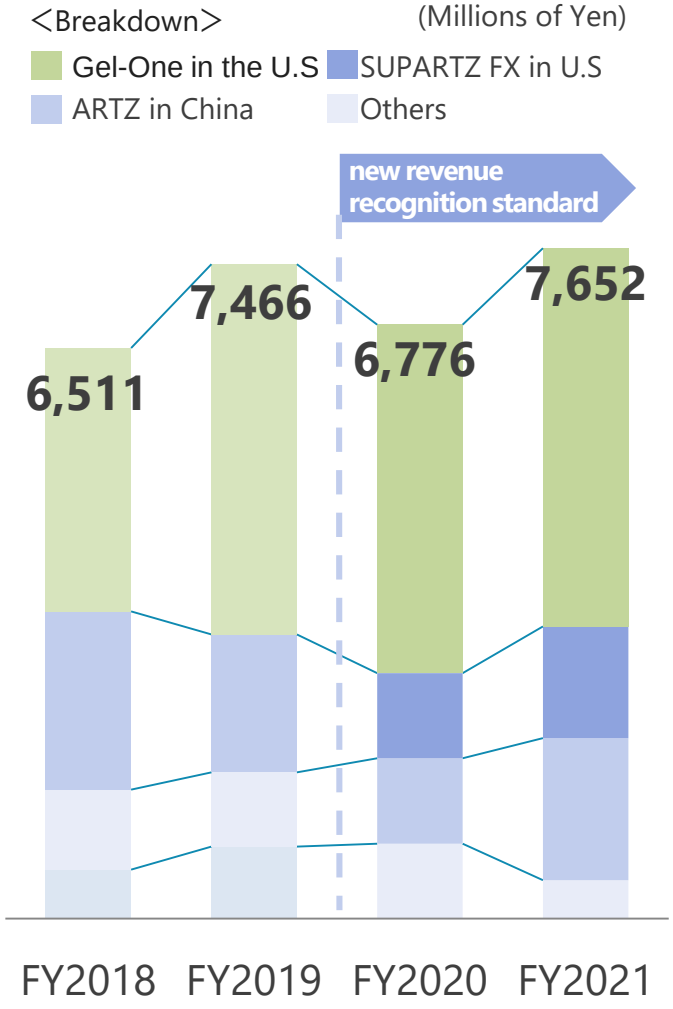
- Sales increase due to a trend toward recovery from the impact of COVID-19 and an increase in the number of new user facilities

FY2022 Assumptions

- Continuation of proper use promotion and patient awareness activities

Overseas Pharmaceuticals 1/2 (FY2021 Results Year-on-Year / value basis)

Overseas Pharmaceuticals Sales trend



FY2021 Results
+12.9% (sales basis)

Sales up due to recovery from the impact of COVID-19 and bringing forward of shipments of SUPARTZ FX and ARTZ in China

＊Foreign exchange impact: approx. + ¥350million

U.S.

Market in U.S.

- Trend toward recovery from the impact of COVID-19
- Continuation of a trend toward preference for products that require a low number of injections

Gel-One

FY2021 Results (approx. +15% on a volume basis)

Local sales：Sharp increase due to recovery from the impact of COVID-19

Seikagaku exports：Sales increase on higher local sales volume

FY2022 Assumptions

Local sales：Forecasting impact from price announcement-related system changes

SUPARTZ FX

FY2021 Results

Local sales：Increase due to recovery from the impact of COVID-19

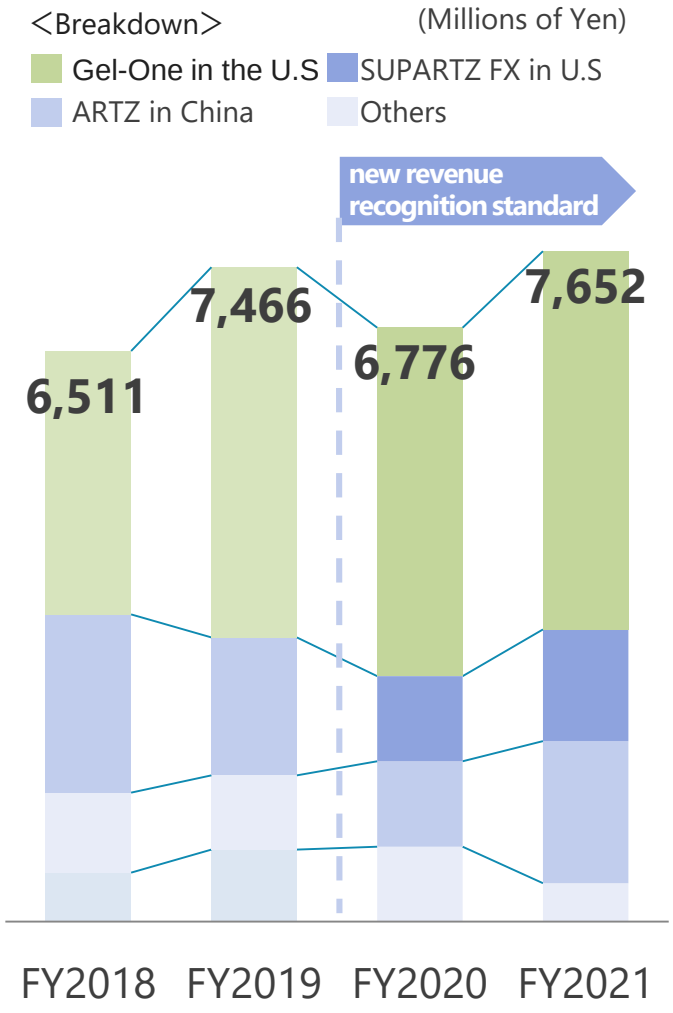
Seikagaku exports：Sharp increase due to shipments brought forward

FY2022 Assumptions

Local sales：Decrease forecasted due to a trend toward preference for products that require a low number of injections

Overseas Pharmaceuticals 2/2 (FY2021 Results Year-on-Year / value basis)

Overseas Pharmaceuticals Sales trend



FY2021 Results
+12.9% (sales basis)

Sales up due to recovery from the impact of COVID-19 and bringing forward of shipments of SUPARTZ FX and ARTZ in China

＊Foreign exchange impact: approx. + ¥350million

China, Other Regions

Market in China

- Start of centralized procurement by multiple provinces and regions
- Impact of COVID-19 lockdowns in some regions

ARTZ in China

FY2021 Results

Local sales： Increase due to growth in regions where successful bids were submitted in the centralized procurement system and higher orders in preparation for sluggish distribution due to the spread of COVID-19

Seikagaku exports：Increase due to higher local sales volume and local inventory buildup

FY2022 Assumptions

Local sales：Possible decrease due to the centralized procurement trend

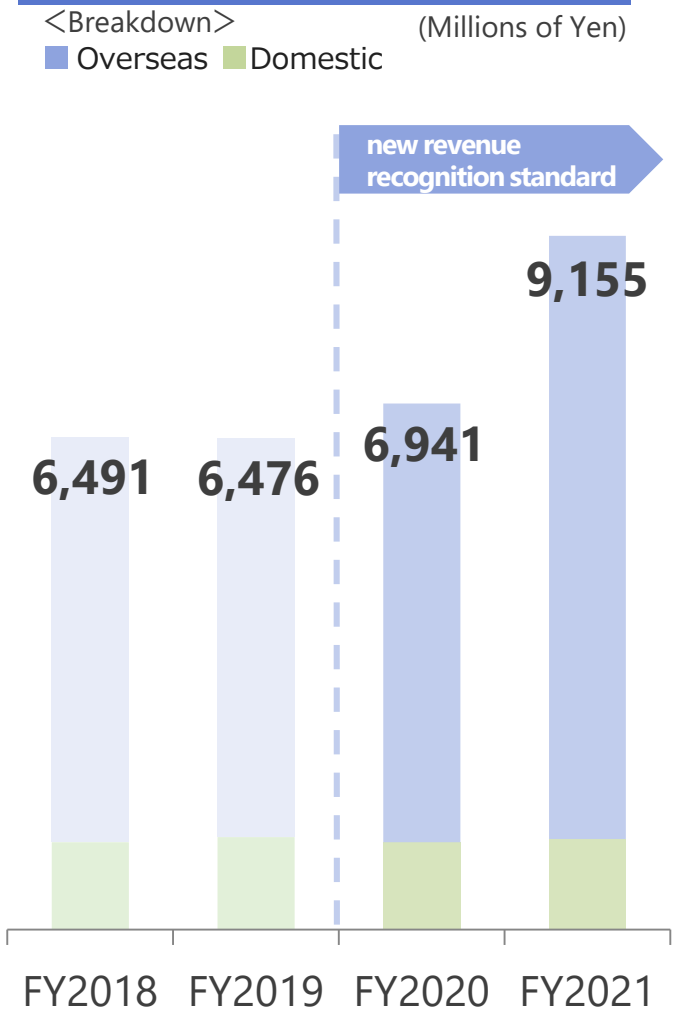
Other Region

Seikagaku exports

FY2021 Results：Sales down in Italy due to a resurgence of COVID-19
Sales up in Taiwan due to the launch of HyLink

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

LAL Business Sales trend



FY2021 Results : +31.9% (Year-on-Year)

＊Foreign exchange impact: approx. +¥230million

Overseas

Increased due to growth of endotoxin detection reagents and glucan detection in vitro diagnostic agents and contract test services at overseas subsidiary ACC

Domestic

Increased due to steady sales of endotoxin detection reagents and other products

FY2022 Assumptions

Overseas

Focus on strengthening sales promotion activities

Domestic

Forecast of steady sales performance

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).

Progress with the Mid-Term Management Plan (FY2019-FY2021)

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**

- Launch of joint function improvement agent JOYCLU (development code: SI-613) : May 2021
  - ▶ June 2021: Issuance of Blue Letter
    Proactive gathering and provision of safety information
    Proceeding with identification of the cause of shock or anaphylaxis
- Completion of subject enrollment for Phase I/II clinical study in the U.S. of SI-722, a treatment for interstitial cystitis : January 2021
- Initiation of pivotal study for SI-449, an adhesion barrier : May 2020
- Completion of subject enrollment for a Phase III additional clinical study in the U.S. of SI-6603, a treatment for lumbar disc herniation : March 2022
- Establishment of SEIKAGAKU NORTH AMERICA CORPORATION (SNA) in Canada : January 2022
- Progress with development of new disease fields and drug discovery modalities utilizing GAG technologies and activities for business domain expansion through open innovation

Progress with the Mid-Term Management Plan (FY2019-FY2021)

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**

- Launch of HyLink, an intra-articular single-injection viscosupplement for the treatment of knee osteoarthritis, in Taiwan : August 2021
- Alliance agreements for SI-613, a treatment for osteoarthritis, concluded with Eisai Co., Ltd.
  Agreement concerning co-development and a marketing alliance in China : April 2020
  Agreement concerning a marketing alliance in South Korea : September 2020:
  - ▶ Consider future development plan while prioritizing identification of the cause of JOYCLU side effects
- Launch of PyroSmart NextGen recombinant LAL reagent, an endotoxin-detecting reagent : April 2021
- Continued to gather and provide information to ensure proper use and safety of HERNICORE
  Start use of HERNICORE at facilities without full-time supervisory physicians accredited by the Japanese Society for Spine Surgery and Related Research (JSSR) : November 2019
  General drug use-results survey interim results announcement : September 2021

Progress with the Mid-Term Management Plan (FY2019-FY2021)

Ⅲ. Productivity improvement reforms

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

- March 2020: Dalton Chemical Laboratories, Inc. (Canada) made a subsidiary
  Gradually switching to in-house production of chemical synthetics and transferring manufacturing of investigational drugs and some Seikagaku products to Dalton
- Maintenance of a system to ensure continuity of business under impact of COVID-19 infection
  Introduction of a work-from-home system and development of the IT environment
- Progress was made with reviews of procurement costs and sales-related expenses
  ▶ Some issues remain with respect to fundamental cost structure improvement

Seikagaku was able to lay a foundation for the next mid-term management plan, positioned as a time for solidifying the profit foundation to return Seikagaku to a growth trajectory

Numerical targets

The spread of COVID-19 infection, nevertheless the Company was able to achieve all numerical targets announced when the plan was formulated

	FY2021 Forecast		FY2021 targets (2019.11)	achievement ratio
	new revenue	old revenue		
Net sales	¥34.8 billion	¥31.2 billion	¥28.3 billion	+10.5%
Ordinary income	¥5.3 billion	¥5.3 billion	¥4.5 billion	+19.9%
SKK EBITDA＊	¥5.5 billion	¥5.5 billion	¥5.0 billion	+10.9%
Overseas sales ratio (excluding royalty income)	56.6%	56.6%	50.0%	+6.6pt

≪Assumptions (2019.11)≫

- 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

Strategic direction for the next mid-term management plan

Further solidification of the profit foundation

- Nurturing of key products
  Market introduction of SI-6603, a treatment for lumbar disc herniation (U.S.)
  Identification of the cause of shock or anaphylaxis following administration of JOYCLU
- Overseas expansion of existing products and products in development, including the LAL business and contract development and manufacturing organization
- Cost reductions, cost structure review

R&D

- Steady advancement of pipelines, including SI-449
- Entry into new domains and new modalities
- Business domain expansion through active utilization of open innovation

Sustainability

- Engagement in business activities centered around material issues

In view of business plans and future earnings forecasts varying substantially depending on the progress to identify the cause of JOYCLU side effects and the development trend in the U.S. of SI-6603, a treatment for lumbar disc herniation, the Company has decided to postpone the announcement planned for May 2022

Announcement of the next mid-term management plan is planned for around autumn 2022

Overview of JOYCLU

Manufacturing and marketing approval in Japan obtained in March 2021
For the indication of osteoarthritis (knee joint and hip joint)
May 19 NHI drug price listing and launch

Product name	JOYCLU®30mg Intra-articular Injection
Generic name	diclofenac etalhyaluronate sodium
Indication	Osteoarthritis (knee joint and hip joint)
Dosage and administration	The usual adult dosage is 1 syringe per dose (30 mg of diclofenac etalhyaluronate sodium) injected intra-articularly every 4 weeks.

Overview of JOYCLU

Improvement of symptoms expected by administration once every 4 weeks
First joint function improvement agent in Japan indicated for the treatment of osteoarthritis of the hip joint

features

- Hyaluronic acid and diclofenac chemically bound using a proprietary technology
- Diclofenac released by hydrolysis in the joint
- Improvement of symptoms of osteoarthritis (knee joint and hip joint) expected by administration once every four weeks
- First joint function improvement agent in Japan indicated for the treatment of osteoarthritis of the hip joint

Expected positioning

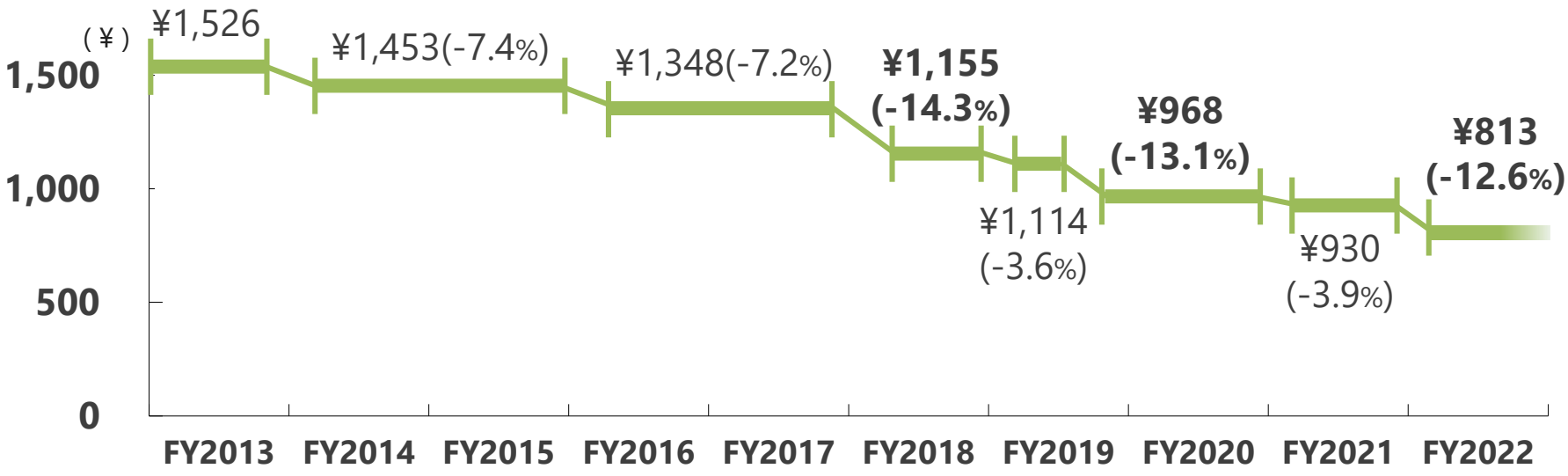
- **Establishment as a new base drug** in the treatment of osteoarthritis alongside existing hyaluronic acid formulations and NSAIDs

  ＜Target Patients＞

  - ▷ People for whom existing hyaluronic acid formulations are insufficiently effective
  - ▷ People who want to avoid NSAIDs, such as oral drugs or patches, in consideration of side effects
  - ▷ People for whom frequent hospital visits are a hardship

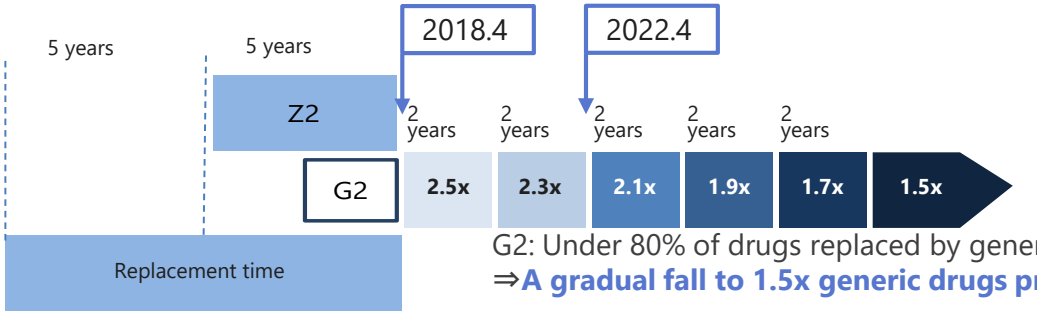
- Provision of **a new treatment option for osteoarthritis of the hip joint**

Trend in NHI Reimbursement Price of ARTZ to Domestic



<Drastic drug pricing reforms>

NHI reimbursement price reduction for long-time listed drugs



G2: Under 80% of drugs replaced by generics

⇒**A gradual fall to 1.5x generic drugs price through 2028**

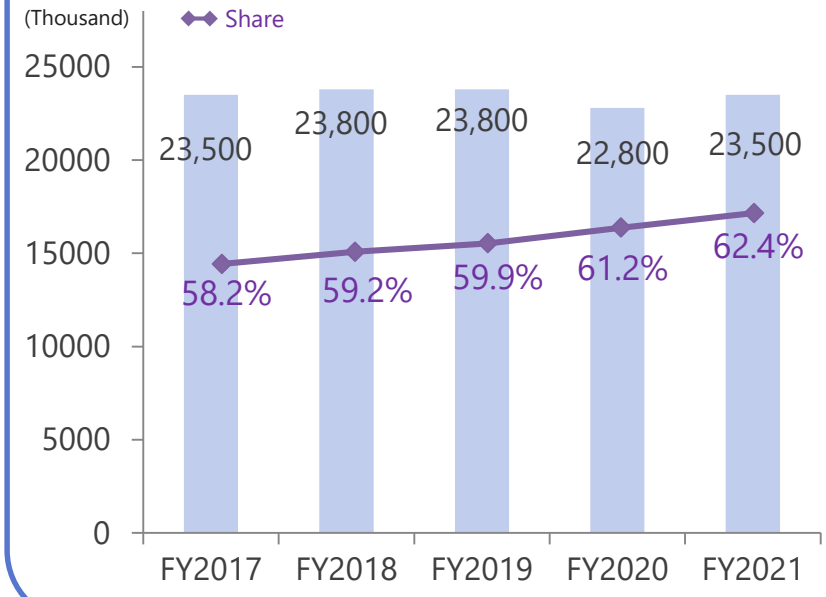
Trend in Deliveries of ARTZ / OPEGAN to Domestic Medical Institutions

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



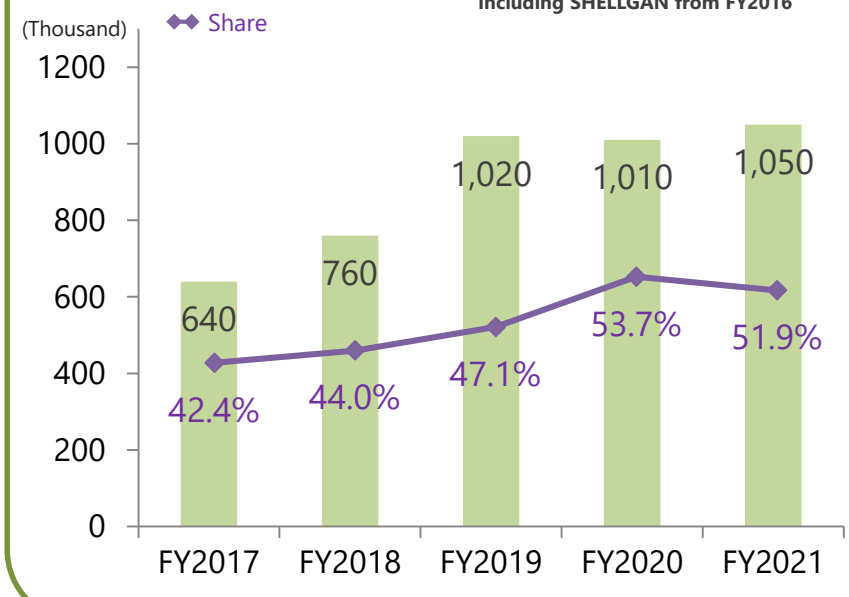
Ophthalmic viscoelastic devices

OPEGAN

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

Trend in unit deliveries to medical institutions

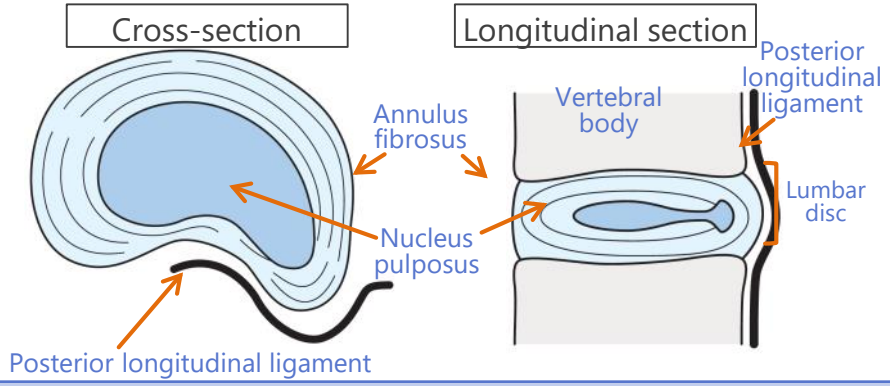
*Including SHELLGAN from FY2016



Four types of lumbar disc herniation

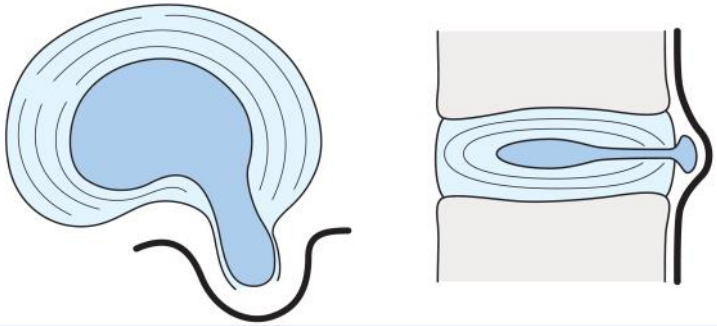
1. Protrusion

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



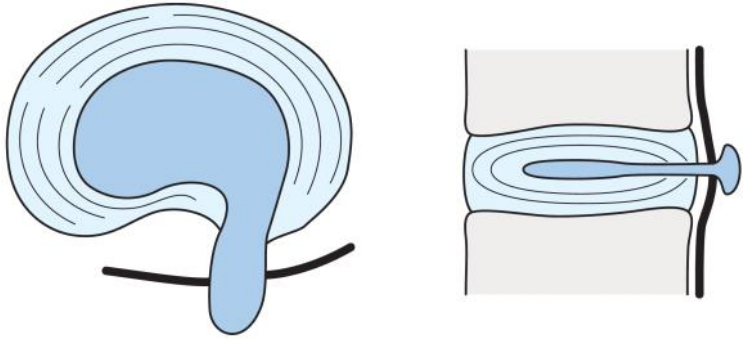
2. Subligamentous extrusion

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



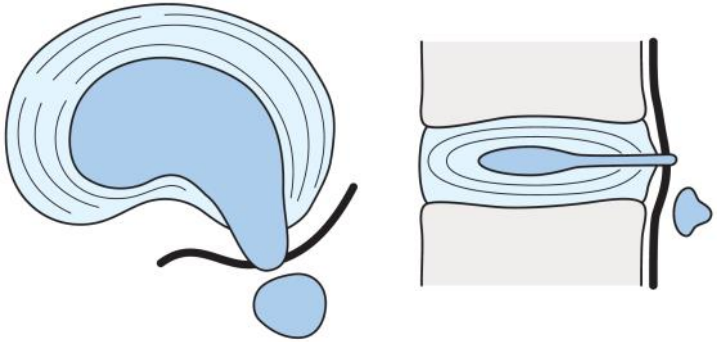
3. Transligamentous extrusion

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

■ 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 family 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 family viscoelasticity comparison

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

Market size of US$950 mil. in 2021 (+8.3% 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.

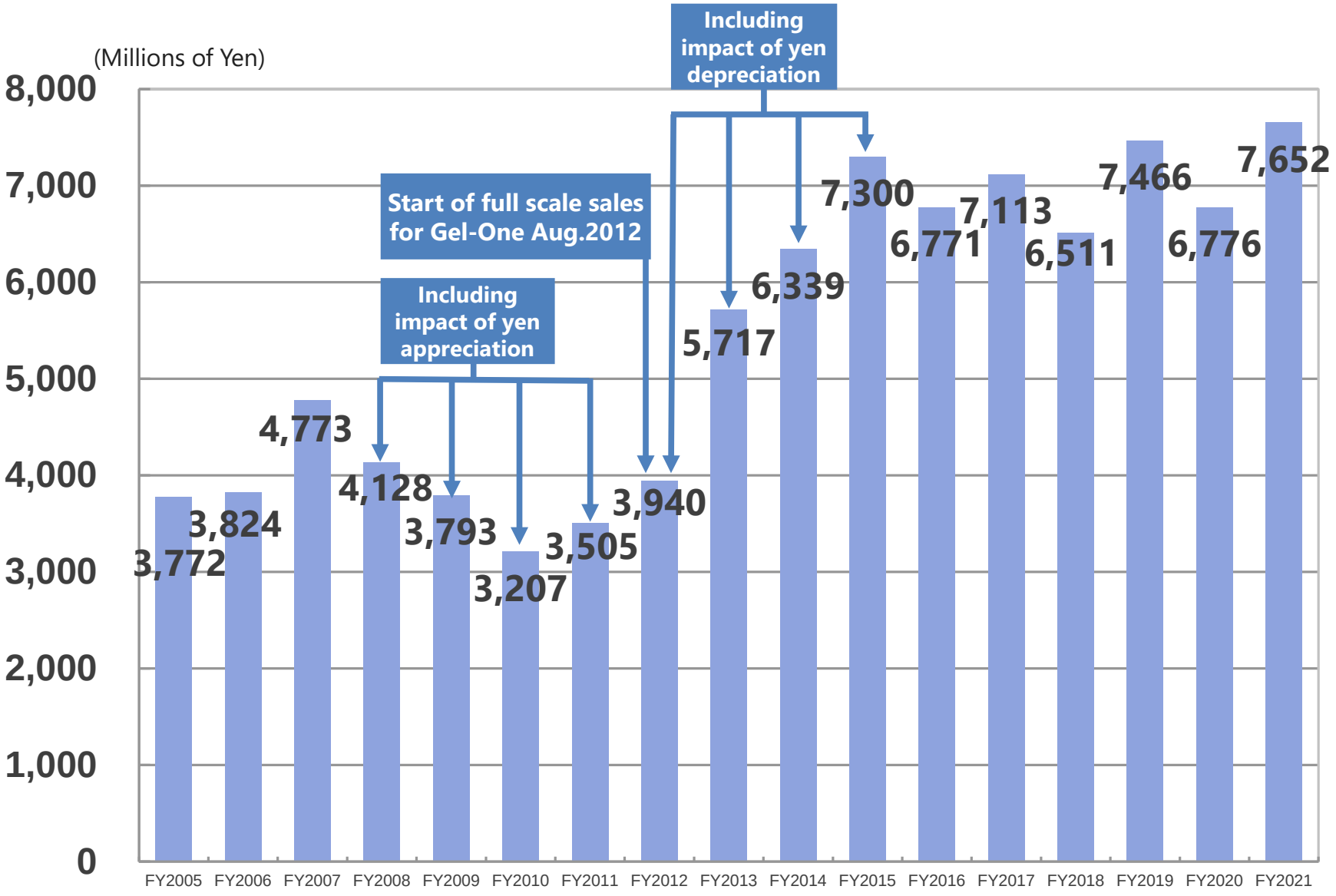
five-injection product
SUPARTZ FX

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

SUPARTZ FX™
sodium hyaluronate

*Figures for 2021, Seikagaku estimates

Trend in Overseas Sales of Hyaluronic Acid Products



Recombinant LAL reagent「PyroSmart NextGen」

April 2021 launch at ACC
Product to be marketed globally, with a launch in Japan planned for May or later in 2021

Product Features

- ▶ Product manufactured using recombinant technology without using blood harvested from horseshoe crabs, a raw material used in traditional products
  - → Ensures continuous product supply
- ▶ Ability to utilize the same test methods and instruments as naturally sourced products
  - → Ensures consistency with endotoxin-testing reagents
  - → A next-generation BET reagent designed to deliver highly reliable quantitation of endotoxins

The LAL Business

Endotoxin detection reagents (Seikagaku Corporation, ACC)

- Manufacture and sale of reagents for detecting endotoxins* in the manufacturing process of pharmaceuticals, etc. (Japan, USA, Europe, etc.)
- Used mainly at pharmaceutical companies
- Launch of PyroSmart NextGen, a recombinant endotoxin detection reagent, in April 2021
- Accelerated global expansion of recombinant reagents

*Since endotoxins exhibit strong pyrogenic activity even in minute amounts, they must be rigorously controlled pursuant to regulations in the manufacture of pharmaceuticals and medical devices.

▶**Global market：Approx. ¥2.5 mil**

(Seikagaku estimate / including related equipment)

Glucan detection in vitro diagnostic agents (ACC)

- Manufacture and sales of in vitro diagnostic agents for measuring the glucan* concentration in blood for use in the diagnosis of deep fungal infections (USA, Europe, etc.)
- Since symptoms of deep fungal infections can be similar to those of COVID-19, the products are used together with COVID tests as necessary to ensure appropriate diagnosis and treatment
- Used mainly at hospitals and testing centers
- Market expansion into additional countries

*(1→3) -β-D-glucans are structural components of the cell walls of fungi, as typified by molds and yeasts.

受託試験サービス（ACC社）

- Contract testing for endotoxin and glucan contamination
- Contributes to quality control at pharmaceutical companies and medical institutions

Outline of Associates of Cape Cod, Inc.

Developed the world's first endotoxin detection reagent and obtained FDA approval in 1977 / Sales network spanning 80 countries

Associates of Cape Cod, Inc.

- Headquarters：Massachusetts, U.S.A.
- Established：1974 (became a Seikagaku subsidiary in 1997)
- Business areas：Manufacture and sale of endotoxin detection reagents and glucan detection in vitro diagnostic agents, provision of contract test services
- Number of employees：263 (as of March 31, 2022)

Recombinant LAL reagent
PyroSmart NextGen®

Endotoxin detection reagents
PYROCHROME®

Exterior of the ACC office

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：147 (2022.3)

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

Outline of SEIKAGAKU NORTH AMERICA CORPORATION

Established new company in Canada, promoting development of Seikagaku pharmaceuticals and medical devices in North America

SEIKAGAKU NORTH AMERICA CORPORATION

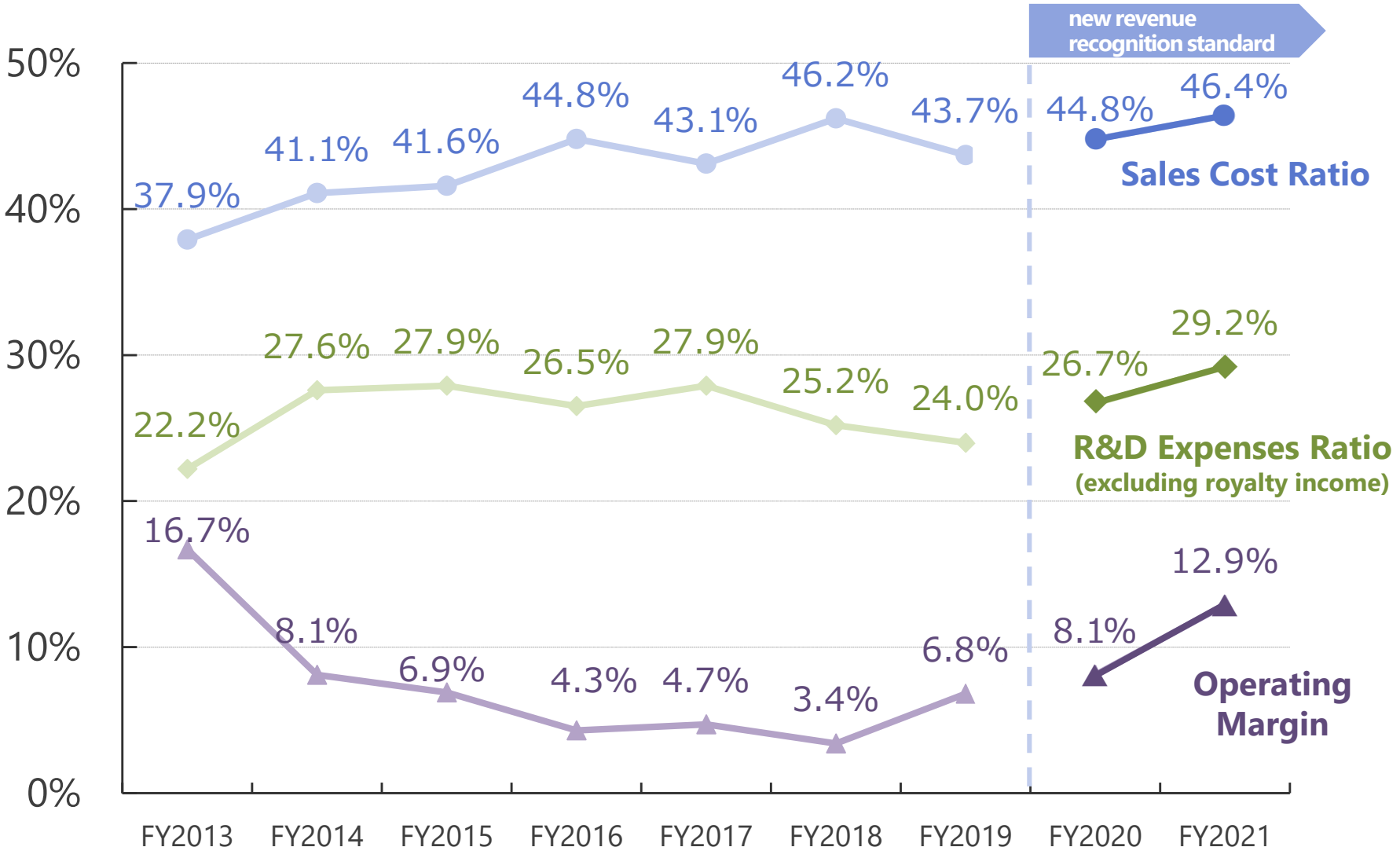
- Location : Toronto, Ontario Province, Canada
- Established : January 25, 2022
- Capital : CAD10
- Business description : Development of pharmaceuticals and medical devices in North America

Purpose of establishment

- Enable responses with fewer constraints on time differences or distance by operating a development base in North America
  - Formulate development plans more closely aligned with local medical environment
  - Create smooth communications with U.S. Food and Drug Administration (FDA) and clinical trial sites

Strengthening the development system in North America.
Aiming to accelerate pharmaceutical and medical device development as well as obtaining of approvals

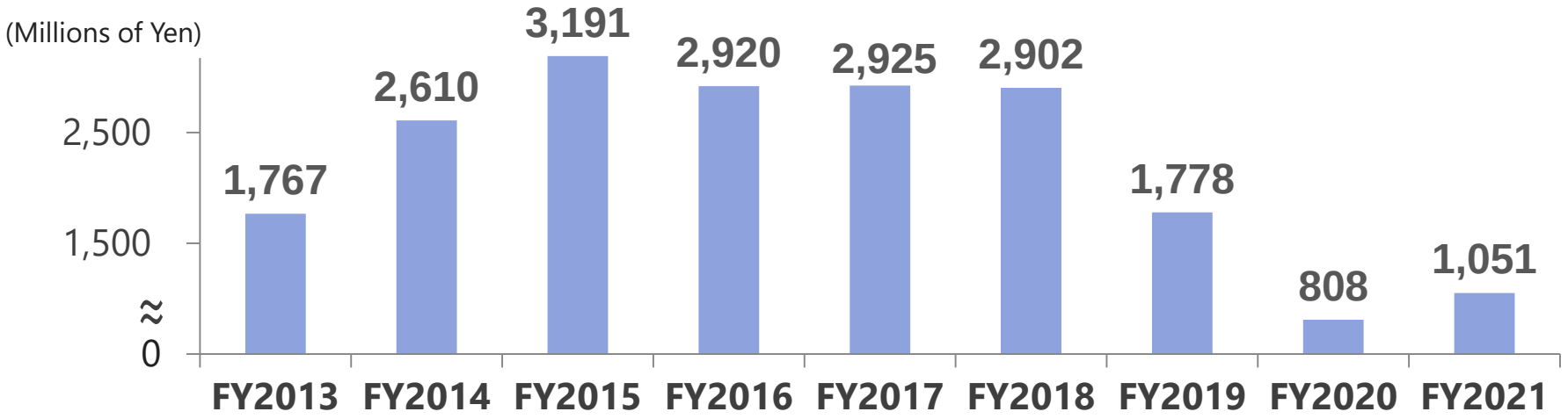
Trend in Financial Index



Trends in Depreciation & Capital Investments

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

■ Trend in Depreciation

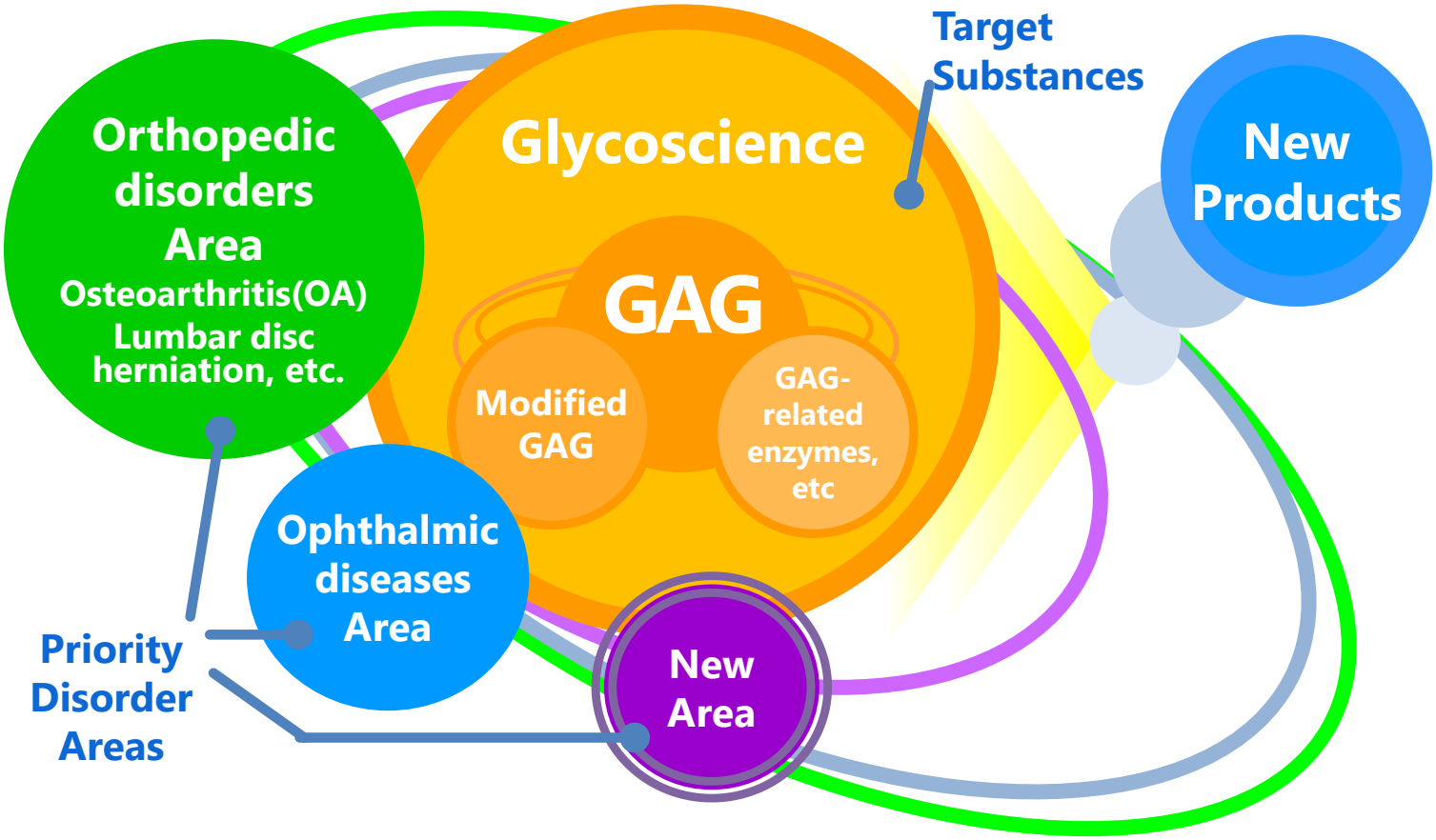


■ Trend in Capital Investments (Millions of Yen)

FY2013	FY2014	FY2015	FY2016	FY2017	FY2018	FY2019	FY2020	FY2021
7,222	2,095	1,975	1,173	1,591	1,310	2,109	2,127	2,194

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)

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.

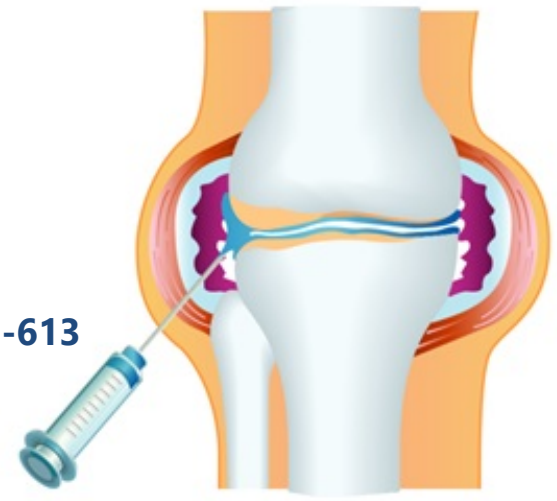
② There is possibility that some factors such as complications biased assessment of leg pain

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 for rapid and sustained improvement of pain and other clinical manifestations associated with osteoarthritis and Enthesopathy

SI-613 Administration image

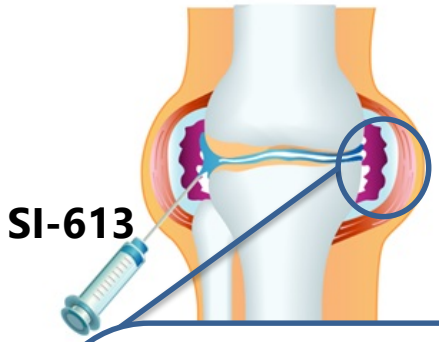


Expected Features

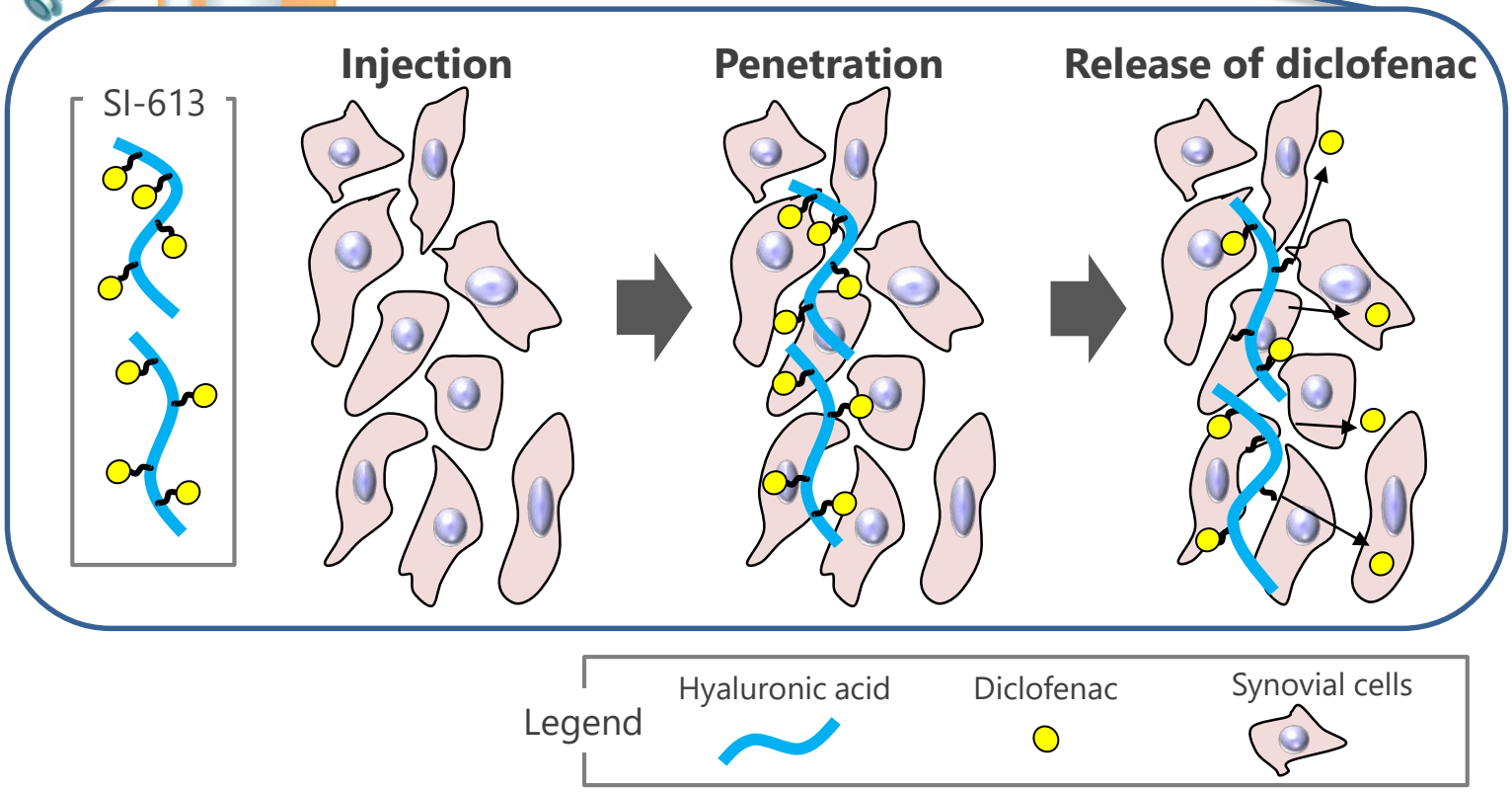
- **Hyaluronic acid and diclofenac (an anti-inflammatory drug) are bound in a formulation designed for gradual release of diclofenac over a fixed period of time**
  Sustained improvement of clinical manifestations, including pain, for 28 days from the day after administration shown in a clinical trial of osteoarthritis patients
- **The first pharmaceutical suitable for treatment of osteoarthritis in the hip joint using a hyaluronic acid formulation**
- **Directly administered to the affected area as an injectable treatment, resulting in low systemic exposure to diclofenac**
  Low risk of systemic side effects

<SI-613 summary>
Dev. code : SI-613 Generic name : Diclofenac Etalhyaluronate Sodium
Indication : Osteoarthritis/Enthesopathy
Method of use : Injection into joint cavity
Estimated patients : 24 million (U.S.) / 47 million (China) / 3.7 million (South Korea)
(Seikagaku estimates)

Sustained Release of Diclofenac in SI-613

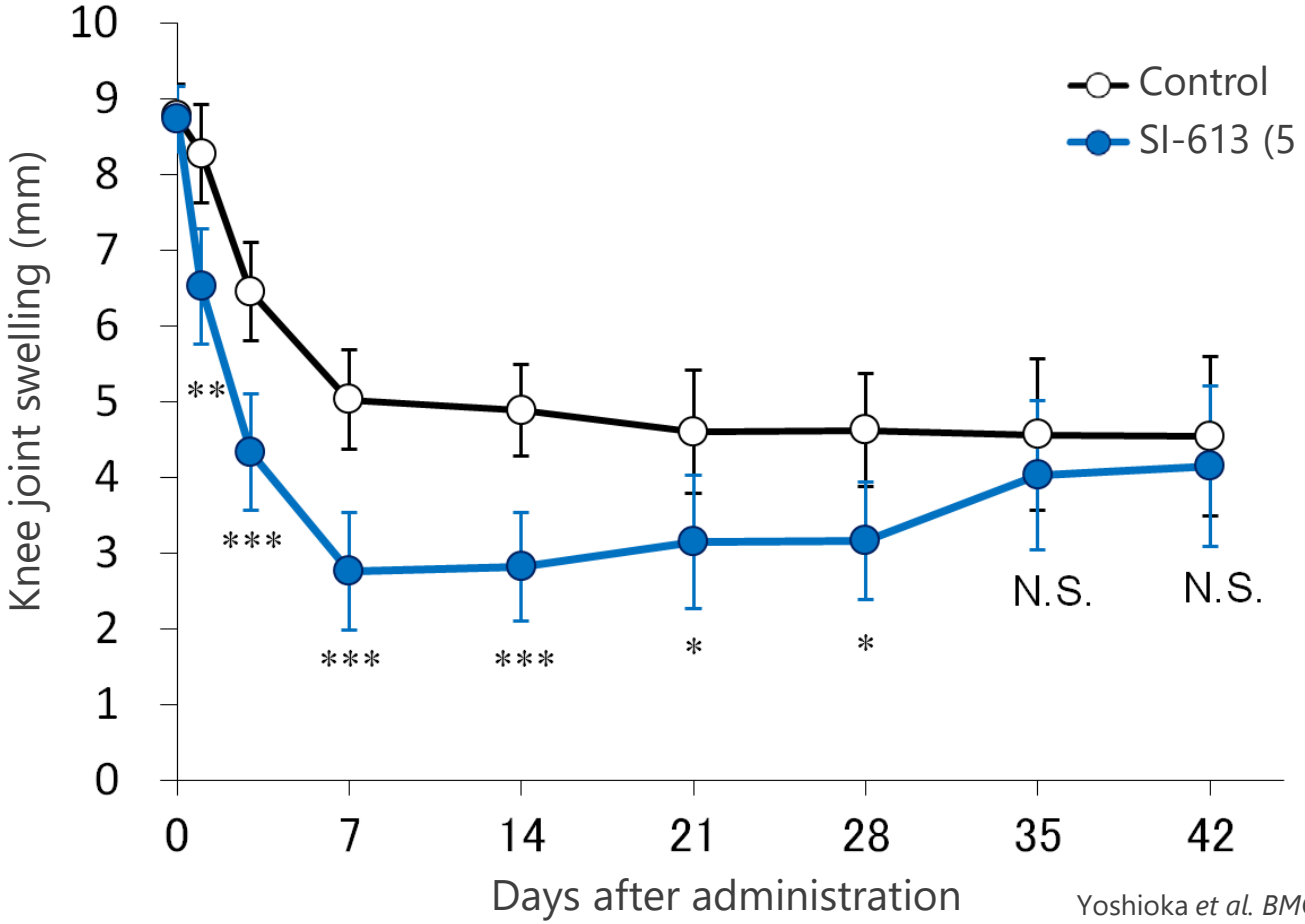


SI-613 (substance name: Diclofenac Etalhyaluronate Sodium) is thought to penetrate the synovial membrane (connective tissue within the articular capsule) and gradually release diclofenac



Results of Non-clinical Study for SI-613

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

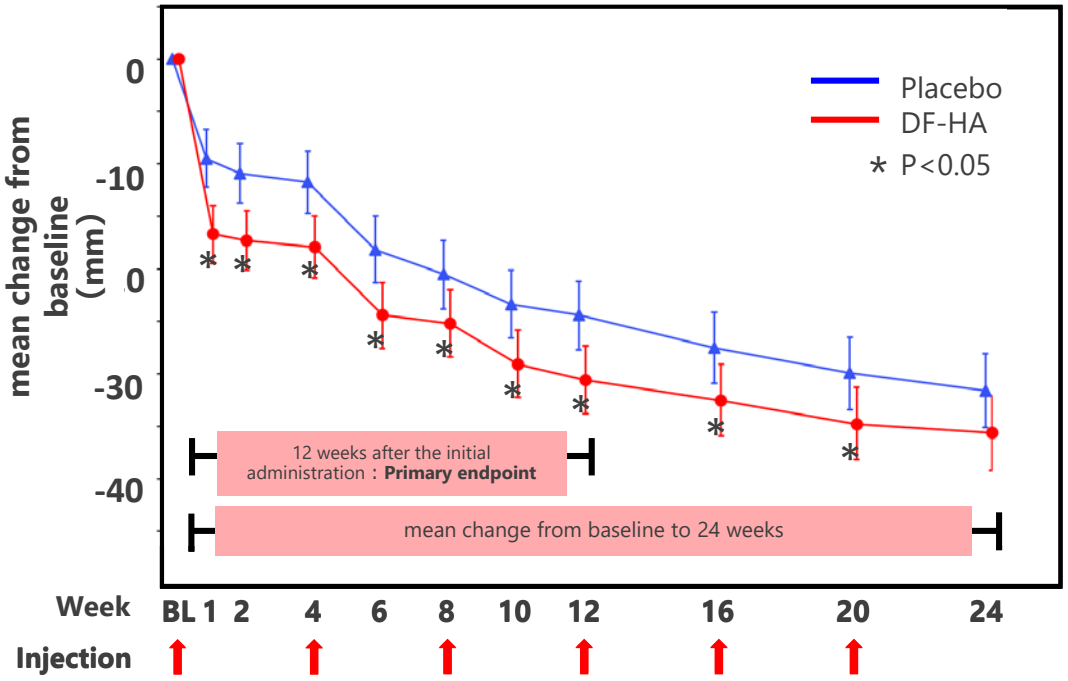


Mean±S.E. (n=20)
*** P<0.001, ** P<0.01, * P<0.05
N.S.(not significant) :
Student's *t*-test with
Holm's correction (vs control)

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

SI-613 (Treatment of Osteoarthritis)

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



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

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

※ DF-HA： Diclofenac Etalhyaluronate Sodium （SI-613）

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

SI-613 (Treatment of Osteoarthritis/Enthesopathy)

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

Outline of Conference Presentation

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

Abstract Number: 3-12-15

The phase III study of Diclofenac Etalhyaluronate Sodium(ONO-5704/SI-613) in osteoarthritis of the knee

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

Primary endpoint: WOMAC pain score

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

Main Secondary endpoints: WOMAC stiffness score and physical function score

Statistically significant difference found versus the placebo group in difference in mean change in WOMAC scores from baseline to 12 weeks after initial administration

Safety evaluation:

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

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-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 III clinical study	240	May. 2022 – Jan. 2023	
SI-722 Interstitial cystitis and bladder pain syndrome	U.S.	Phase I / II clinical study (NCT04208087)	32	Mar. 2020 – Jan. 2021	Maximum observed plasma concentration
SI-449 Adhesion Barrier	Japan	Pivotal study (Field of gastroenterological surgery) (JapicCTI-205343)	130	Jun. 2020 – Dec. 2022	Efficacy
SI-449 Adhesion Barrier	Japan	Pilot study (Field of gynecology) (jRCT2072210100)	10	Dec. 2021 – Sep. 2022	Usability, Safety

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

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

Contract Status by R&D Theme

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

Development Code Indication	Develop-ment Location	Sales Partner	Total Amount of Milestone Royalties (of which, in upfront payment)
SI-6603 Lumbar Disk Herniation	U.S.	Ferring Pharmaceuticals (Switzerland)	Max. US $95 million (US $5 million)
SI-613 Japan: Osteoarthritis U.S. : Knee Osteoarthritis	Japan	Ono Pharmaceutical Co., Ltd.	Max. ¥12.0 billion (¥2.0 billion)
	U.S.	Searching	—
	China	Eisai Co., Ltd.	—
	Korea	Eisai Co., Ltd.	—
SI-613-ETP Enthesopathy	Japan	Ono Pharmaceutical Co., Ltd.	*included in the above
SI-614 Dry eye	U.S.	Searching	—
SI-722 Interstitial cystitis	U.S.	—	—
SI-449 Adhesion Barrier	Japan	—	—

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 ***40%*** of our employees (Non-consolidated base)
- 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 73.7%

Ophthalmic Surgical Aids

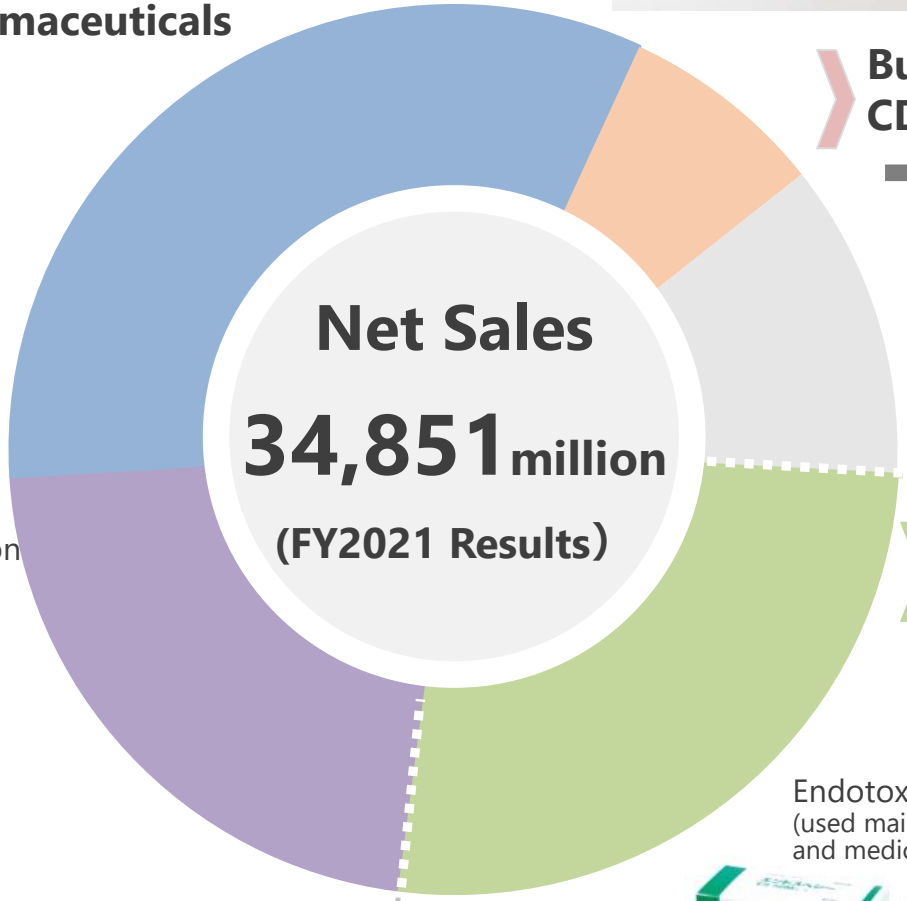
Domestic Pharmaceuticals ➡ 32.8%

Joint Function Improving Agents

Treatment for lumbar disc herniation

Overseas Pharmaceuticals ➡ 22.0%

Joint Function Improving Agents



Bulk Products/ CDMO ➡ 7.5%

Bulk Products

Royalty income ➡ 11.4%

LAL Business 26.3%

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

SEIKAGAKU CORPORATION

Main Hyaluronic Acid (HA) Products

ARTZ® Joint function improving agent by multiple injections

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

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

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

■ Cautionary Notes

This material contains forward-looking statements regarding future management strategies or performance forecasts. These descriptions are based on judgments derived from information that is currently available to Seikagaku and are subject to risk and uncertainty. Actual results and developments may differ significantly from these descriptions due to various factors.Information about pharmaceutical products or medical devices (including products currently in development) contained in this material is not intended to constitute an advertisement or medical advice.

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