Financial Results for the 3rd Quarter of Fiscal Year 2020 (April 1, 2020 – December 31, 2020)



(TSE:4548)

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< Cautionary Notes >

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

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

Overview for 3Q of FY2020

	3Q FY2020	3Q FY2020 Year-on-Year		(Reference) FY2020 Full Year Forecasts		
(Millions of Yen)	Results	Change	% of Change	FY 2020 Forecasts	Degree of Progress	
Net sales	20,813	-2,426	-10.4%	27,500	75.7%	
Operating Income	1,459	-1,806	-55.3%	850	171.7%	
Ordinary Income	2,113	-1,754	-45.4%	2,050	103.1%	
Extraordinary Loss	_	-12,441	_	_	-	
Net Income	1,879	+11,661	_	1,700	110.6%	
R&D Expenses (Ratio to net sales)	5,380 (25.9%)	+923 (+6.7pt)	+20.7%	7,700 (28.0%)	69.9%	
Average Exchange Rate (1US\$)	¥106.11	¥-2.56		^{4Q forecast} ¥103.00		
		3Q FY2020 Results	3Q FY2019 Results	(Reference) FY2020 Forecasts		
Net Income per Share		¥33.31	-¥173.40	¥30.13		

Net sales by Business Segment (3Q of FY2020)

(Millions of Yen)		Millions of Yen)	3Q FY2020 Results	Year-on- Year	% of Change	
Net sales		Net sales	20,813	-2,426	-10.4%	
	Pharmaceuticals		15,853	-2,495	-13.6%	
ľ		Domestic Pharmaceuticals	9,617	-1,853	-16.2%	
		Overseas Pharmaceuticals	4,700	-1,345	-22.3%	
		Bulk Products /CDMO	1,535	+703	+84.6%	
	L	AL Business	4,960	+68	+1.4%	
(0	verseas sales)	9,648	-494	-4.9%	

* Foreign exchange impact on overall net sales: approx. -120million yen

Domestic Pharmaceuticals

- ► ARTZ (Joint-function improving agent)
- Overall market contraction, reflecting a decrease in outpatient services due to the impact of COVID-19 infection (-7.5%)
 Deliveries to medical institutions down (-5.9%)
 Market share increase (+1.0 pt)
- Seikagaku sales down due to NHI drug price reductions
- ► OPEGAN series (Ophthalmic viscoelastic devices)
- Market contraction, reflecting a decrease in the number of surgeries due to the impact of COVID-19 infection (-13.0%)
 - Deliveries to medical institutions up due to the impact of competing product shipment adjustments (+1.8%)
- Seikagaku sales up, with higher volume compensating for NHI drug price reductions

MucoUp

(Submucosal injection agent for endoscopic surgery)

- Seikagaku sales down due to a low-price sales offensive for a competing product and a decrease in the number of surgeries
- ► HERNICORE (Treatment for lumbar disc herniation)
- Deliveries to medical institutions steadily increasing
- Seikagaku sales down, reflecting a high level of shipments in the same period of the previous fiscal year

Net sales by Business Segment (3Q of FY2020)

(Millions of Yen)	3Q FY2020 Results	Year-on- Year		
Net sales	20,813	-2,426	-10.4%	
Pharmaceuticals	15,853	-2,495	-13.6%	
Domestic Pharmaceuticals	9,617	-1,853	-16.2%	
Overseas Pharmaceuticals	4,700	-1,345	-22.3%	
Bulk Products /CDMO	1,535	+703	+84.6%	
LAL Business	4,960	+68	+1.4%	

* Foreign exchange impact on overall net sales: approx. -120million yen

Overseas Pharmaceuticals

*Foreign exchange impact on Overseas Pharmaceuticals: approx. -60 million yen

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

- Local sales volume up from 2Q onward due to easing of measures such as postponement of nonurgent and non-emergency medical procedures (approx. +4.0%)
- Seikagaku sales down due to the substantial impact of lower 1Q shipments



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

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

- Local sales volume down sharply due to continuation of the trend toward preference for products that require a low number of injections coupled with the impact of COVID-19 infection
- Seikagaku sales down as well

► ARTZ in China (Multiple injection)

- Local sales volume of ARTZ up, reflecting minimal market impact of curtailed outpatient services, which continue in some areas of China
- Seikagaku sales down due to the impact of shipment adjustments

Net sales by Business Segment (3Q of FY2020)

	(Millions of '	Yen)	3Q FY2020 Results	Year-on- Year	% of Change
	Net sales		20,813	-2,426	-10.4%
	Pharmaceu	ticals	15,853	-2,495	-13.6%
	Domestic Pharmaceu	ıticals	9,617	-1,853	-16.2%
	Overseas Pharmaceu	ıticals	4,700	-1,345	-22.3%
	Bulk Prod /CDMO	ucts	1,535	+703	+84.6%
	LAL Busine	ess	4,960	+68	+1.4%
(Overseas sales)		9,648	-494	-4.9%	

* Foreign exchange impact on overall net sales: approx. -120million yen

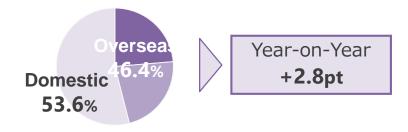
Bulk Products / CDMO

- Sales up due to the addition of sales from contract manufacturing at Dalton Chemical Laboratories, despite lower sales of bulk products.
- * Starting from the second quarter under review, the sales of Dalton Chemical Laboratories, Inc., which became a subsidiary in March 2020, are included in the pharmaceuticals business segment

LAL Business

- *Foreign exchange impact on LAL Business: approx. -60million yen
- Sales up slightly on growth in domestic and overseas sales of Bacterial Endotoxin Testing (BET) and Clinical Diagnostic (Fungitell) reagents
- Impact of COVID-19 infection limited at this time
- * LAL business: Manufacturing and sale of endotoxin-detecting reagents used in quality control for pharmaceuticals and medical equipment

Overseas Sales Ratio



Income for 3Q of FY2020 (Year-on-Year)

(Millions of Yen)	3Q FY2020 Results	Year-on- Year	% of Change
Net sales	20,813	-2,426	-10.4%
Cost of Sales (Cost of Sales ratio)	9,191 (44.2%)	-867 (+0.9pt)	-8.6%
SGA expenses	10,162	+247	+2.5%
R&D Expenses (to Net sales ratio)	5,380 (25.9%)	+923 (+6.7pt)	+20.7%
Operating Income (to Net sales ratio)	1,459 (7.0%)	-1,806 (-7.1pt)	-55.3%
Ordinary Income	2,113	-1,754	-45.4%
Extraordinary loss	-	+12,441	-
Net Income	1,879	+11,661	_
Depreciation	566	-1,045	-64.9%

Operating Income

Cost of Sales Ratio (+0.9pt)

 Cost of sales ratio up due to NHI drug price reductions and change in sales composition, despite lower depreciation due to non-recurrence of impairment loss on property, plant and equipment related to the pharmaceuticals business

SGA Expenses (+247)

- Decrease in operation expenses including sales promotion expenses (-802)
- R&D expenses increase due to costs of additional clinical study of SI-6603 in the U.S. (+923)

Ordinary Income

Non-operating Income / Expenses (+51)

- Royalty income related to overseas products increases (+195)
- Decrease in gains on sales of investment securities (-185)

Net Income

Extraordinary loss

 Impairment loss recognized in prior-year period (12,441)



Revised Forecasts in FY2020

	FY2020			FY2019	(Reference)	
(Millions of Yen)	Revised Forecasts	Change	% of Change	Change	% of Change	Degree of 3Q Progress
Net sales	27,500	+850	+3.2%	-1,142	-4.0%	75.7%
Operating Income	850	+300	+54.5%	-1,110	-56.6%	171.7%
Ordinary Income	2,050	+650	+46.4%	-1,931	-48.5%	103.1%
Net Income	1,700	+550	+47.8%	+12,539	_	110.6%
R&D Expenses (Ratio to net sales)		+300 (+0.2pt)	+4.1%	+822 (+4.0pt)	+12.0%	69.9%
Average Exchange Rate (1US\$)	4Q forecast ¥103.00	-¥2.00		-¥5.75		

	FY2020 Revised Forecasts	FY2020 Initial Forecasts	FY2019 Results
Net Income per share	¥30.13	¥20.38	-¥192.15
Dividend per share	¥20.00	¥20.00	¥26.00
Dividend Payout ratio	66.4%	98.1%	_

Revised Net Sales in FY2020 (Comparison with the initial forecast)

	FY2020 Revised	Initial Forecasts			
(Millions of Yen)	Forecasts	Change	% of Change		
Net sales	27,500	+850	+3.2%		
-Pharmaceuticals	20,650	+400	+2.0%		
-LAL Business	6,850	+450	+7.0%		
OperatingIncome (Ratio to net sales)	850 (3.1%)	+300 (+1.0pt)	+54.5%		
Ordinary Income	2,050	+650	+46.4%		
Net Income	1,700	+550	+47.8%		
Cost of Sales ratio	44.4%	+0.1pt	-		
R&D Expenses (Ratio to net sales)	7,700 (28.0%)	+300 (+0.2pt)	+4.1%		
Depreciation	800	-	-		

Net sales

Revised upward, reflecting softer-than-expected impact of COVID-19 infection on overseas pharmaceuticals and overseas sales in the LAL business * Foreign exchange impact on overall net sales : approx. -5million yen

Operating Income

Revised upward, with higher sales compensating for higher R&D expenses

SGA Expenses (approx. +200) :

Operating expenses down, R&D expenses up due in part to subject recruitment expenses for a clinical trial in the U.S. for SI-6603 (+300)

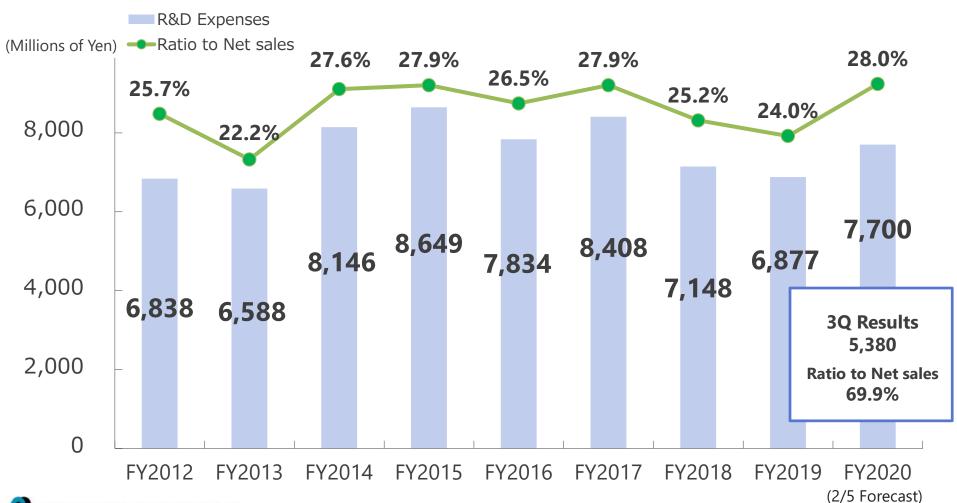
Ordinary Income/Net Income

Revised upward, reflecting an increase in nonoperating income

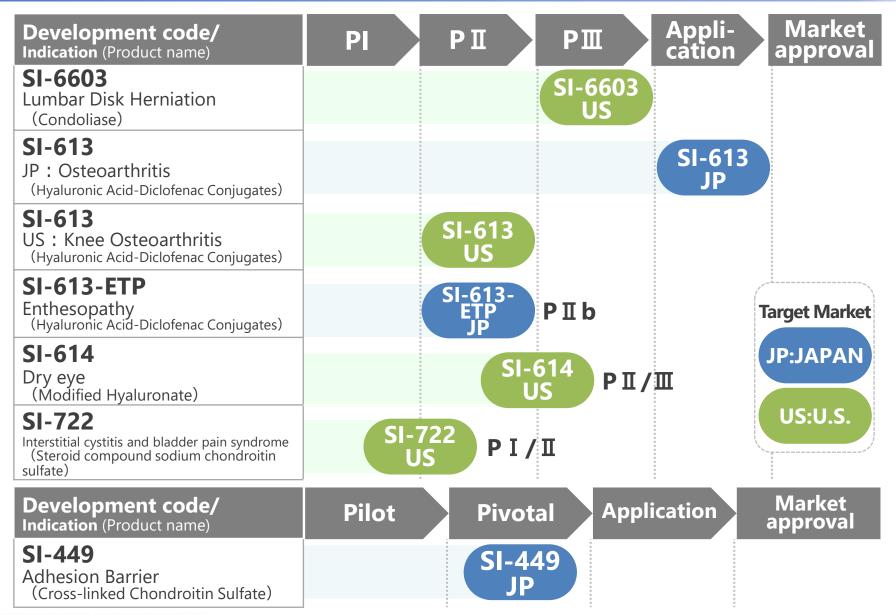
Non-operating income (approx. +400):
Projected increase in royalty income related to overseas products

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 (Treatment for Lumbar Disc Herniation)

Steady progress in subject enrollment thanks to various measures Endeavoring to minimize delays due to COVID-19 infection

Development status

- ► Additional Phase III study in the U.S. Intiated February 2018. Extending enrollment by two years, aiming for November 2022 completion
 - **⇒**Delay of anticipated due to the spread of COVID-19 infection
 - Impacted by discontinuation of the study at some medical institutions and subjects postponing hospital visits
 - Possibility of a further delay if a lockdown is ordered in a state where many trial sites are located
 - ⇒We plan to minimize delays as utilization rates at treatment facilities have been on a recovery since July
 - Implement effective advertising campaigns to recruit subjects
 - Advance early start-up of treatment facilities connected with local CROs

Measures to promote enrollment

- Increase number of subjects
- Advertising suited to treatment facility requirements
- Strengthen coordination with medical institutions and increase patient introductions
- Relax enrollment standards
- Increase trial facilities
 - Link-up with support vendors specializing in facility selection to increase number of facilities

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SI-613 (Treatment of Osteoarthritis)

Responding to NDA review in Japan (osteoarthritis) Approval recommended by PAFSC Second Committee

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
- ▶ January 2021 Deliberation at a meeting of the Second Committee on New Drugs of the Pharmaceutical Affairs and Food Sanitation Council (PAFSC) Approval for treatment in the knee joint and hip joint recommended

<SI-613 summary>

Dev. code : SI-613 Generic name : Diclofenac Etalhyaluronate Sodium

Indication : Osteoarthritis/Enthesopathy

Method of use : Injection into joint cavity

Estimated patients: 6.2 million (Seikagaku estimates)

SI-613 (Treatment of Osteoarthritis)

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

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

► Analysis of Phase II clinical study results is complete

Proceeding with partner selection in parallel with examination of Phase III study

SI-613 (osteoarthritis of the knee) China

► Agreement with Eisai on a co-development and marketing alliance in China, in April 2020

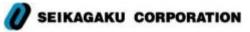
Proceeding with preparation of a clinical development plan

SI-613 (osteoarthritis of the knee) South Korea

► Agreement with Eisai for a market alliance

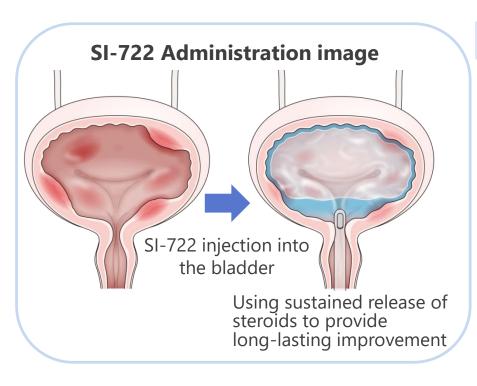
Aims to obtain approval by South Korea of the clinical study data and approval content in Japan

Plans to apply for South Korean approval following the obtaining of approval by Japan



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

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



Development status

- **▶** U.S. Phase I/II / Starting November 2019
 - Started subject administration in March 2020
 - ⇒Subject enrollment completed in January 2021
 Set to proceed with analysis of study results and consideration of future clinical trial plan

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

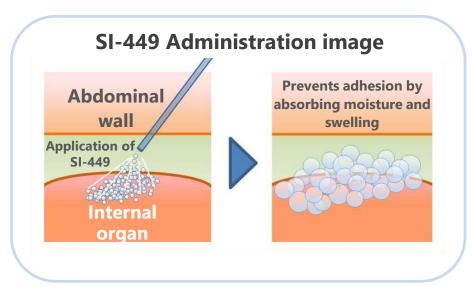
Estimated U.S. patients: 1.3 million (Seikagaku estimates)



SEIKAGAKU CORPORATION

SI-449 (Adhesion Barrier / Medical Device)

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



Development status

- ► Japan pivotal study / Starting May 2020
 - Evaluated for effectiveness, safety, and usability
 - ⇒Plans delayed by restrictions on visits to facilities due to COVID-19 infection effects
 - ⇒ Treatment countermeasures in progress under a remote set-up
- Proceed with development with a view to global development; Start of U.S. pilot study under review

Promising features

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

<SI-449 summary>

Dev. Code : SI-449 Generic name: Cross-linked chondroitin sulfate

Product name : Adhesion barrier

Method of use: Intra-abdominal application (powdered formulation)

Adhesion barrier market: Japan: ¥13 billion, Global: ¥100 billion (Seikagaku estimates)



SEIKAGAKU CORPORATION 16

Basic Policy on Profit Distribution

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

Shareholder returns

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

Business investment

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

Strategic investment

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

	FY2016	FY2017	FY2018	FY2019	FY2020 (Forecast)
Net Income per share	¥31.55	¥69.30	¥39.76	¥-192.15	¥30.13
Annual Total Dividend	¥31.00 [*]	¥26.00	¥26.00	¥26.00	¥20.00
Dividend Payout Ratio	98.3%	37.5%	65.4%	_	66.4%

Appendix



Forecasts (Net sales) in FY2020

	FY2020	Year-on-Year			
(Millions of Yen)	Forecasts	Change	% of Change		
Net sales	27,500	-1,142	-4.0%		
Pharmaceuticals	20,650	-1,516	-6.8%		
Domestic Pharmaceuticals	12,000	-1,679	-12.3%		
Overseas Pharmaceuticals	6,750	-716	-9.6%		
Bulk Products /CDMO	1,900	+880	+86.3%		
LAL Business	6,850	+373	+5.8%		
(Overseas sales)	13,650	+736	+5.7%		

Net sales

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

Pharmaceuticals

Domestic Pharmaceuticals:

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

Overseas Pharmaceuticals:

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

Bulk Products/CDMO:

Sales up after adding in contract development and manufacturing organization

LAL Business

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

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

ARTZ (Joint-function improving agent)

2Q FY2020 Results

• Market contracts from a drop in outpatient services due to COVID-19

► FY2020 Forecasts

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

growth rate: -8.0%

Market growth rate: -10.1%

Market share: 60.7%

(+1.3pt)

OPEGAN (Ophthalmic viscoelastic devices) **%including SHELLGAN**

2Q FY2020 Results

- Market contracts in conjunction with fewer surgeries due to COVID-19
- Added volume and share due to shipment adjustments for competing products

growth rate: +5.6%

Market growth rate: -13.7%

Market share: 54.2%

(+9.9pt)

► FY2020 Forecasts

• Aiming for additional expansion through promotion of switching from competing products (growth rate: +8.4% / Market share: 57.9%)

HERNICORE (Treatment for lumbar disc herniation)

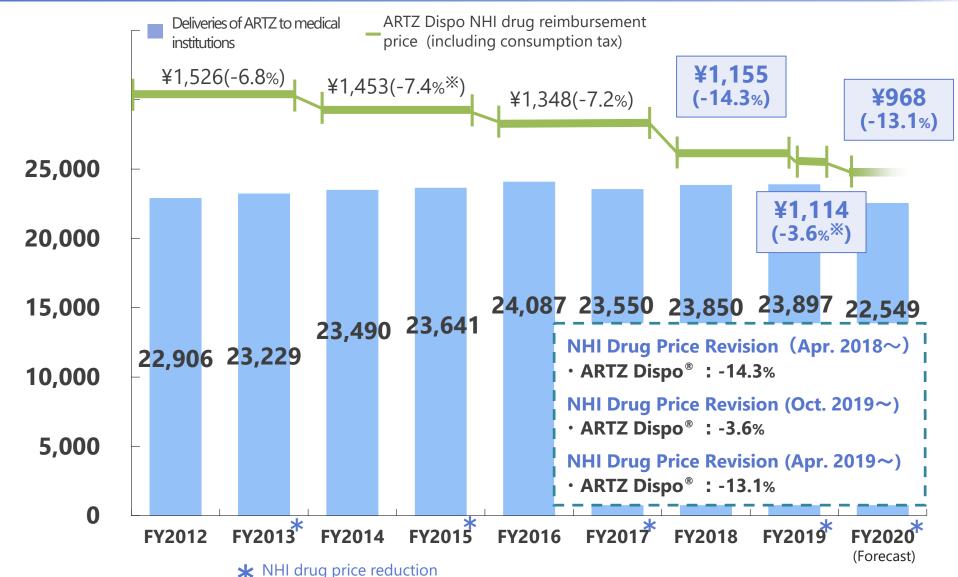
2Q FY2020 Results

• Increased deliveries to medical institutions due to the addition of new user facilities

► FY2020 Forecasts

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

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



Extraordinary drug price revision in FY2019 accompanying a consumption tax increase (October 2019)

** excluding the impact of consumption tax hike

^{*} There is no change in forecast announced on November 16, 2020.

Trend in Deliveries of ARTZ / OPEGAN to Domestic Medical Institutions

Joint-function improving agent

ARTZ



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

Trend in unit deliveries to medical institutions



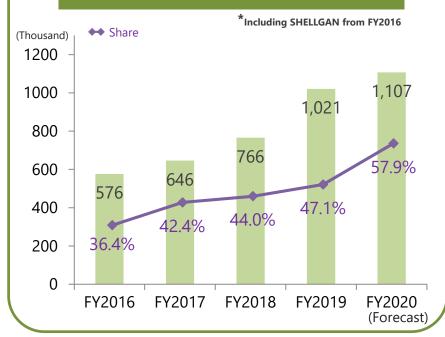
Ophthalmic viscoelastic devices

OPEGAN

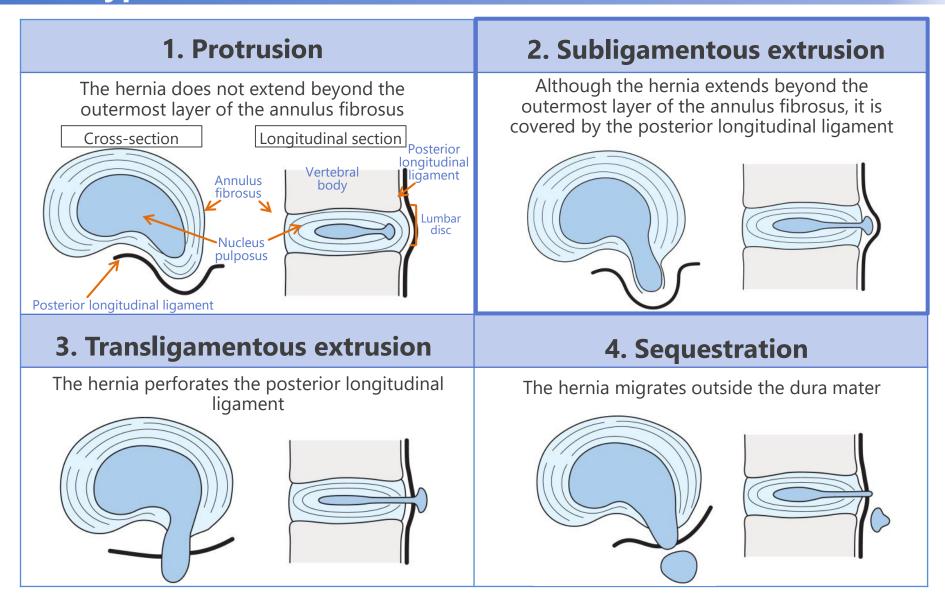


- The first domestically HA formulation
- Used in cataract surgery to anterior chamber expansion
- Distributor: Santen Pharmaceutical

Trend in unit deliveries to medical institutions



Four types of lumbar disc herniation



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



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

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



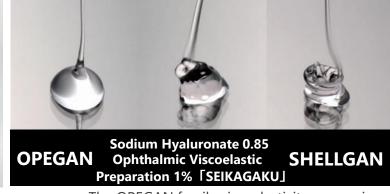
Ophthalmic viscoelastic devices SHELLGAN



■ Product SHELLGAN Outline

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





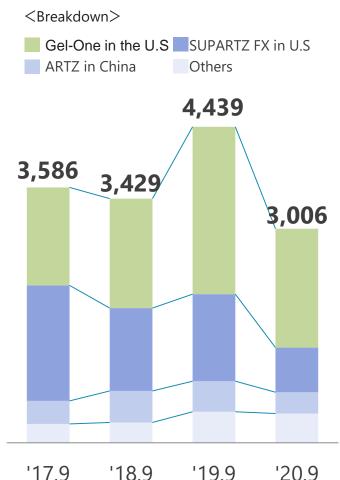
The OPEGAN series, used mainly in cataract surgery

The OPEGAN family viscoelasticity comparison

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

Overseas Pharmaceuticals Sales trend

(Millions of Yen)



2Q FY2020 Results -32.3%

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

U.S.

U.S. Market

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

Sales in the U.S.

Gel-One: Increase due to market recovery (+5% volume-based)

Due to successful to switch from competing products and market expansion in single injection products, trending above prior year since June

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

► Seikagaku exports

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

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

Overseas Pharmaceuticals Sales trend

(Millions of Yen)



2Q FY2020 Results -32.3%

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

China, Other Regions

China Market

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

Local sales of ARTZ in China
 Market on a recovery towards prior-year levels

Seikagaku exports

Seikagaku sales down on adjusted shipments to distributors of ARTZ in China

Seikagaku sales decline marked by a lack of recovery for local outpatient services in Italy

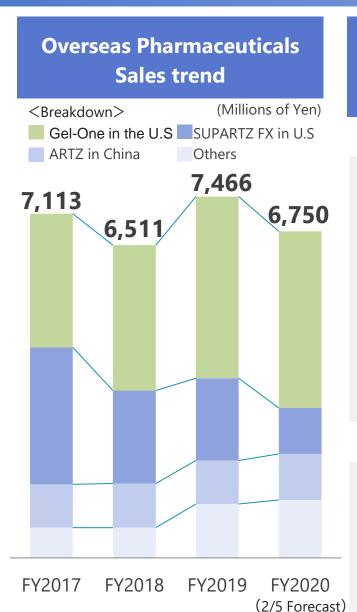
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Overseas Pharmaceuticals (FY2020 Forecast Year-on-Year / value basis)



FY2020 Forecast -9.6%

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

U.S.

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

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

China, Other Regions

- Local sales of ARTZ in China
 A sales increase from a return to market normal
- Seikagaku exports
 Italy a large decrease
 China and Taiwan largely in line with last year

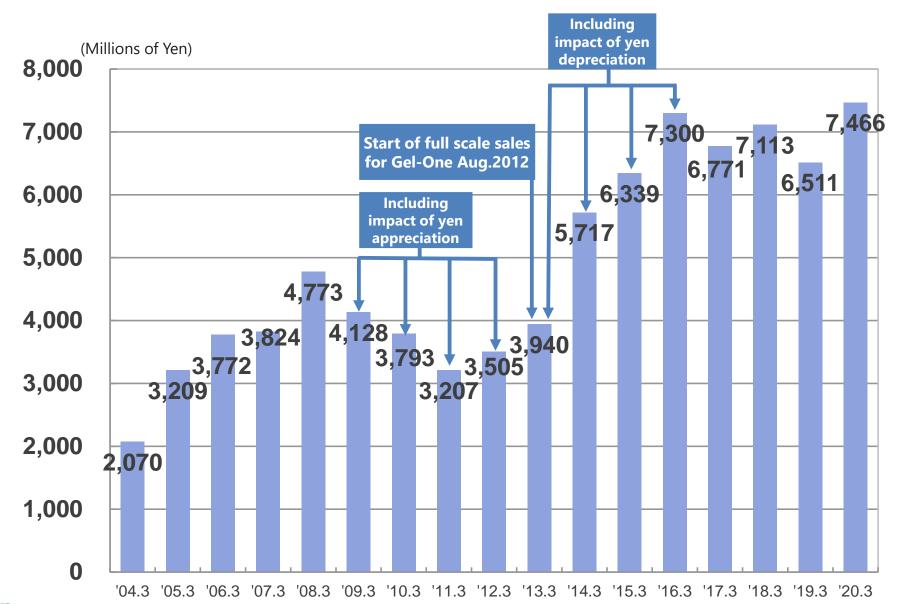
Market Situation of Hyaluronic Acid Products in the U.S.

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)



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



(Seikagaku estimate, including required equipments)

Associates of Cape Cod, Inc. (ACC)

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

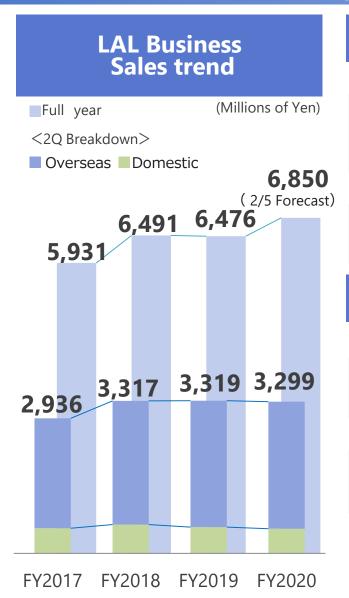


Endotoxin detection reagents (for quality control of pharmaceuticals and medical devices)





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



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

Overseas

* Foreign exchange impact: approx. - ¥50million

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

Domestic

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

FY2020 Forecasts: +5.8% (Year-on-Year)

Overseas

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

Domestic

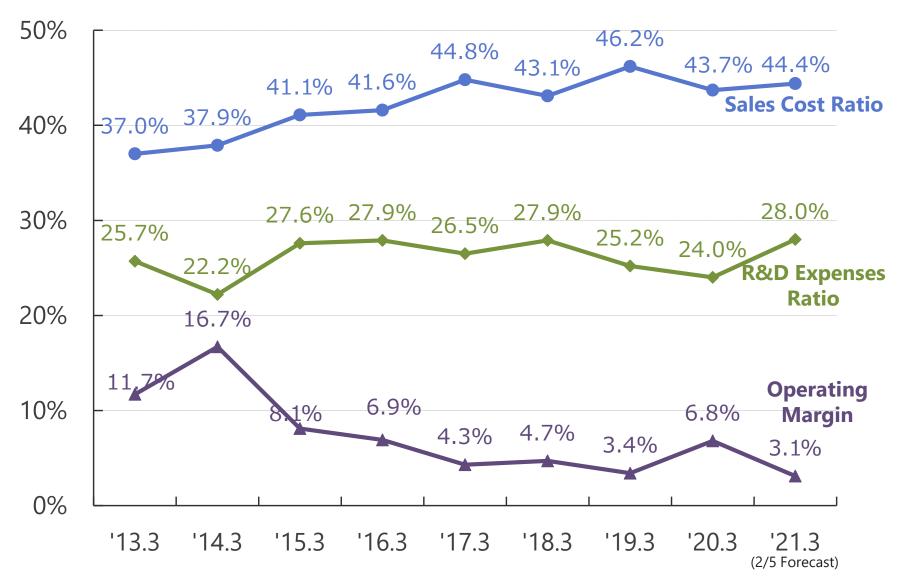
Lower sales due to a change in equipment delivery periods as a result of COVID-19

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

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



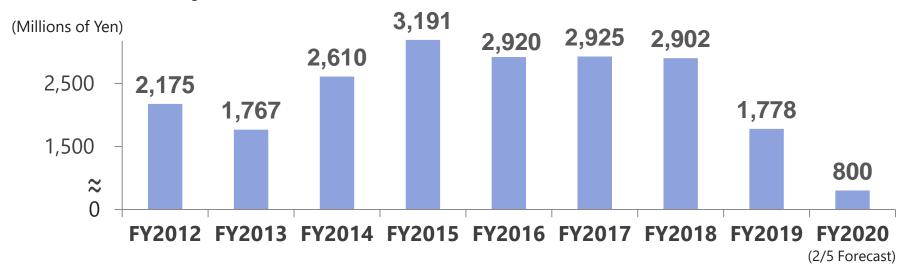
Trend in Financial Index



Trends in Depreciation & Capital Investments

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

■ Trend in Depreciation

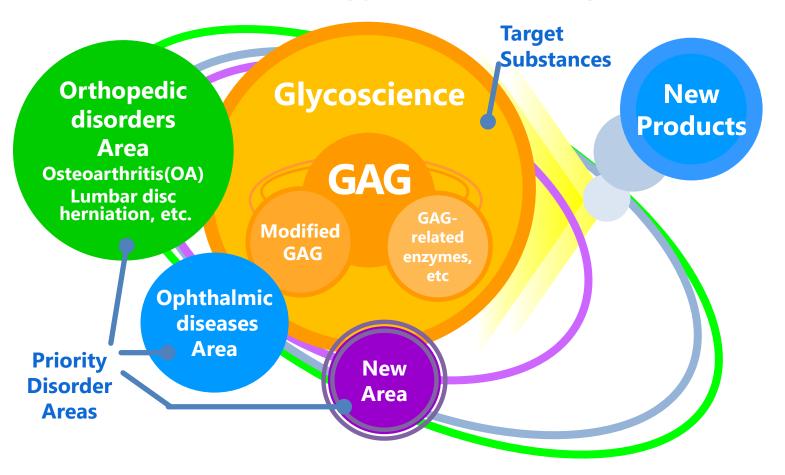


■ Trend in Capital Investments (Millions of Yen)

FY2012	FY2013	FY2014	FY2015	FY2016	FY2017	FY2018	FY2019	FY2020 (2/5 Forecast)
9,164	7,222	2,095	1,975	1,173	1,591	1,310	2,109	2,300

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 chemicalcross-linking
- Physio-chemical functions including viscoelasticity and retention
- Bioactive substances (degrading enzymes)

GAG

New Drugs

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

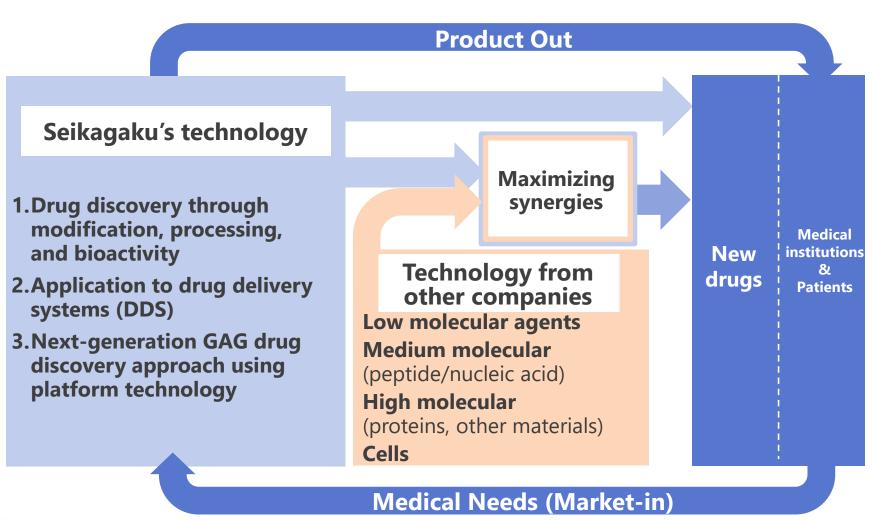
- Conversion from natural GAG to fermented GAG
- Expanding the field of sugar chain drug discovery Applying to glycobiology

SI-613 SI-614



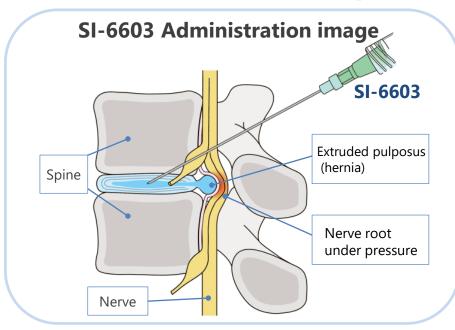
Accelerating Innovative Drug Discovery Using The Open Innovation Strategy

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



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)



SEIKAGAKU CORPORATION

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



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>

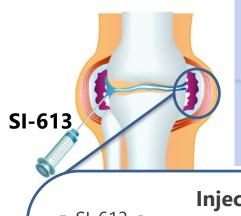
Dev. code : SI-613 Generic name : Diclofenac Etalhyaluronate Sodium

Indication : Osteoarthritis/Enthesopathy

Method of use : Injection into joint cavity

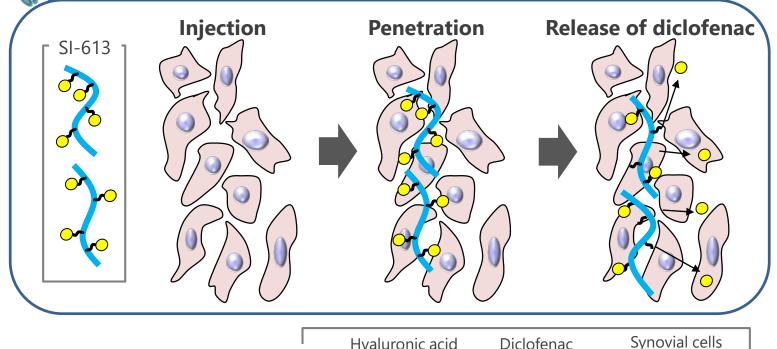
Estimated patients: 6.2 million (Seikagaku estimates)

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

Diclofenac



Hyaluronic acid

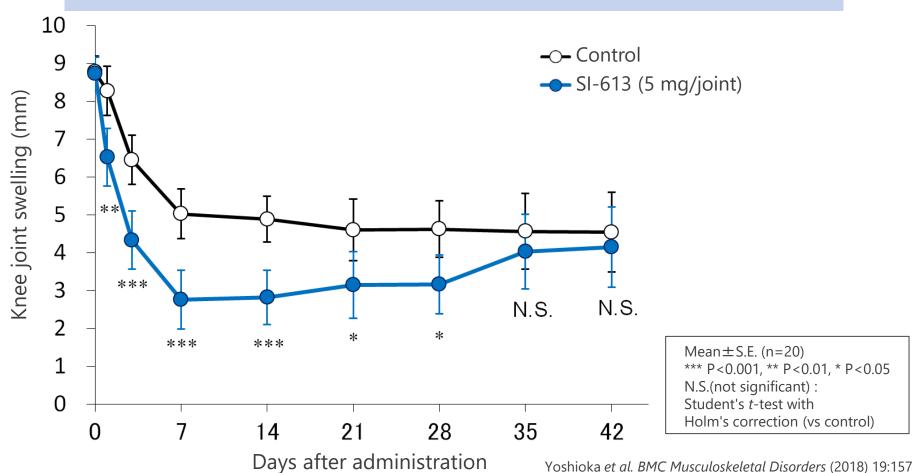
Legend

https://doi.org/10.1186/s12891-018-2077-8

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Results of Non-clinical Study for SI-613

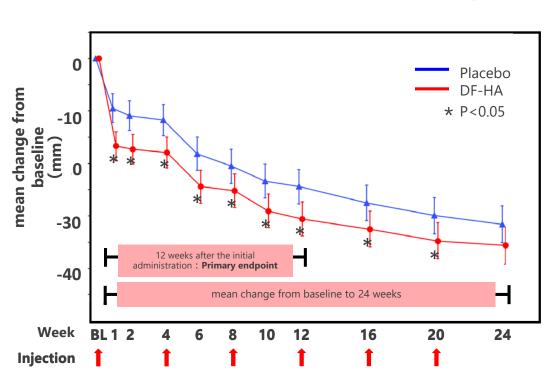
Results of non-clinical study:
Anti-inflammatory effect of SI-613 on antigen-induced arthritis in rabbits



EIKAGAKU CORPORATION

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

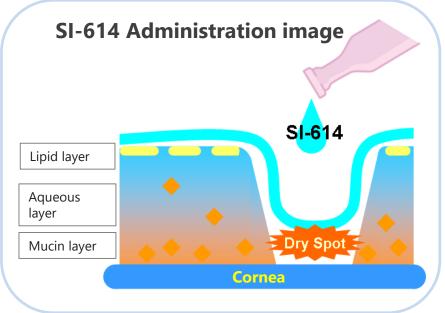
Main Secondary endpoints: WOMAC stiffness score and physical function score
Statistically significant difference found versus the placebo group in difference in mean change in WOMAC scores from baseline to 12 weeks after initial administration

Safety evaluation:

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

SI-614 (Treatment of Dry Eye)

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



Development status

- **▶** U.S. : P II/III
 - January 2015: Phase II/III clinical study completed
 - Plan to conduct a PIII study after a sales partner has been decided

infection Promising features

- ►SI-614 Improves symptoms of dry eye by protecting the ocular surface and promoting corneal epithelial wound healing
- ▶ Dry Eye is a multifactorial disease, and Seikagaku aims to provide a treatment option based on a new mechanism unavailable from existing products

<SI-614 summary>

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

Product name : Dry eye Formulation : Ophthalmic solution

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

Clinical Study Information

Development code/ Indication	Develop- ment Location	Clinical Study Title (Study ID)	Target Enroll- ment	Estimated Period	Primary End Point (Primary Follow-up period)
SI-6603 Lumbar Disk Herniation	U.S.	Phase III additional study (NCT03607838)	320	May. 2018 – Nov. 2022	Leg pain (13 weeks)
SI-613 Osteoarthritis	Japan	Phase III Knee confirmatory study (JapicCTI-173537)	440	Feb. 2017 – Jan. 2019	WOMAC(Knee pain) (12 weeks)
		Phase III study for four sites (JapicCTI-173678)	280	Aug. 2017 – Jun. 2019	Daily pain diary (12 weeks)
		Long-term administration study(JapicCTI-183855)	160	Feb. 2018 – Sep. 2019	Safety (52 weeks)
SI-613-ETP Enthesopathy	Japan	Late-stage Phase II clinical study (JapicCTI-173758)	240	Oct. 2017 – Oct. 2018	Pain in motion (4 weeks)
SI-613 Knee Osteoarthritis	U.S.	Phase II clinical study (NCT03209362)	80	Oct. 2017 – Nov. 2018	WOMAC(Knee pain) (12 weeks)
SI-614 Dry eye	U.S.	Phase II / III clinical study (NCT02205840)	240	Jul. 2014 – Nov. 2014	Corneal staining score, Symptom score (28 days)
SI-722 Interstitial cystitis and bladder pain syndrome	U.S.	Phase I / II clinical study (NCT04208087)	32	Mar. 2020 – Jan. 2021	Maximum observed plasma concentration
SI-449 Adhesion Barrier	Japan	Pivotal study (JapicCTI-205343)	130	Jun. 2020 – Dec. 2022	efficacy

Note: The table shows data registered (or planned to be registered) on clinical trial information websites. The information is updated from time to time. Refer to the websites for details and the latest information. (The websites can be accessed from the trial ID links.)

- Japan Pharmaceutical Information Center(JAPIC) http://www.clinicaltrials.jp/user/cteSearch_e.jsp
 University hospital Medical Information Network (UMIN) Center http://www.umin.ac.jp/ctr/index.htm

• ClinicalTrials.gov https://clinicaltrials.gov/ct2/search
Note: Actual enrollments or trial periods may differ from targets and plans due to various factors.



Contract Status by R&D Theme

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

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

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

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

Response to the COVID-19 Infections

Measures to prioritize assurance of safety for employees and related parties

Production

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

R&D

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

Seikagaku's actions

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

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 knowhow 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

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



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

Our Business Segment

Pharmaceutical Business

77.4%

Domestic Pharmaceuticals

→ 47.8%

Joint Function Improving Agents



Overseas
Pharmaceuticals
⇒26.1%



Net Sales

28,642 million

(FY2019 Results)

Ophthalmic Surgical Aids



Bulk Products



Bulk Products

⇒ 3.6%



LAL Business 22.6%



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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.)



Exploring the Innovative Promise of Glycoscience

■ 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.



