Financial Results for the 2nd Quarter of Fiscal Year 2021 (April 1, 2020 – September 30, 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 2Q of FY 2021

	2Q FY2021	Year-on-Year		(Refer	
(Millions of Yen)	Results	Change	% of Change	FY 2021 Forecasts	Degree of Progress
Net sales	20,530	+7,253	+54.6%	32,200	63.8%
Operating Income	6,038	+5,249	+665.0%	4,550	132.7%
Ordinary Income	6,393	+5,315	+492.9%	4,650	137.5%
Net Income	5,019	+4,057	+422.2%	3,650	137.5%
R&D Expenses (excluding royalty income)	3,802 (22.4%)	+266 (-4.4pt)	+7.5%	7,900 (28.3%)	48.1%
Average Exchange Rate (1US\$)	¥109.80	+2.88			
		2Q FY2021 Results	2Q FY2020 Results	(Reference) FY2021 Forecasts	
Net Income	per Share	¥89.07	¥17.04	¥64.83*2	
SKK EBITDA*1		6,513million yen	1,198million yen	5,750million yen	

SEIKAGAKU CORPORATION

 $[\]ast\,1$ SKK EBITDA : A profit indicator that adds depreciation to operating income $\ast\,2$ Including the impact of the acquisition of treasury stock in July 2021

Net sales by Business Segment (2Q of FY2021)

	(Millions of Yen)	2Q FY2021 Results	Year-on- Year	% of Change
	Net sales	20,530	+7,253	+54.6%
	Pharmaceuticals	16,136	+6,158	+61.7%
ĺ	Domestic Pharmaceuticals	6,805	+843	+14.2%
	Overseas Pharmaceuticals	4,449	+1,472	+49.5%
	Bulk Products /CDMO	1,330	+382	+40.3%
	Royalty Income	3,550	+3,459	+3,818.3%
	LAL Business	4,394	+1,095	+33.2%
(Overseas sales)	9,135	+2,889	+46.3%

* Foreign exchange impact on overall net sales: approx. +210million yen

Domestic Pharmaceuticals

- ► ARTZ (Joint-function improving agent)
- Higher unit deliveries to medical institutions increased sales, which offset NHI drug price reductions
- **▶ JOYCLU** (Joint-function improving agent)
- May 19, 2021 launch
- Made ongoing efforts to provide information to ensure appropriate use
- ► OPEGAN series (Ophthalmic viscoelastic devices)
- Sales down due to NHI drug price reductions and reduced shipments from a high level in 2Q FY2020
- ► MucoUp

(Submucosal injection agent for endoscopic surgery)

- Sales increased due to earlier-than-planned shipments
- ► HERNICORE (Treatment for lumbar disc herniation)
- Sales up due to higher unit deliveries to medical institutions



HERNICORE:

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

Net sales by Business Segment (2Q of FY2021)

(M	illions of Yen)	2Q FY2021 Results	Year-on- Year	% of Change
ı	Net sales	20,530	+7,253	+54.6%
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(Ov	erseas sales)	9,135	+2,889	+46.3%

Overseas Pharmaceuticals

*Foreign exchange impact on Overseas Pharmaceuticals: approx. +130 million yen

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

• Sales up due to increase in local sales volume



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

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

 In addition to increase in local sales volume, sales up due to advance shipments to avoid distribution risks

► ARTZ in China (Multiple injection)

 In addition to increase in local sales volume, sales up due to a concentration of shipments before end of 2Q

Net sales by Business Segment (2Q of FY2021)

(1	Millions of Yen)	2Q FY2021 Results	Year-on- Year	% of Change
	Net sales	20,530	+7,253	+54.6%
	Pharmaceuticals	16,136	+6,158	+61.7%
	Domestic Pharmaceuticals	6,805	+843	+14.2%
	Overseas Pharmaceuticals	4,449	+1,472	+49.5%
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	LAL Business	4,394	+1,095	+33.2%
(C	verseas sales)	9,135	+2,889	+46.3%

^{*} Foreign exchange impact on overall net sales: approx. +210million yen

Bulk Products / CDMO

*Foreign exchange impact on Bulk Products/CDMO: approx. +100million yen

 While bulk product sales fell, those by overseas subsidiary CDMOs, etc. increased

Royalty Income

- Huge increase
- * Royalty income reclassified from non-operating income to net sales beginning in FY2021

LAL Business

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

 Sales up on growth in sales of Bacterial Endotoxin Testing (BET), contract services and Clinical Diagnostic (Fungitell) reagents

Overseas Sales Ratio (excluding royalty income)



Income for 2Q of FY2021

(Millions of Yen)	2Q FY2021 Results	Year-on- Year	% of Change
Net sales	20,530	+7,253	+54.6%
Cost of Sales (excluding royalty income)	7,357 (43.3%)	+1,237 (-3.1pt)	+20.2%
SGA expenses	7,134	+766	+12.0%
R&D Expenses (excluding royalty income)	3,802 (22.4%)	+266 (-4.4pt)	+7.5%
Operating Income (to Net sales ratio)	6,038 (29.4%)	+5,249 (+23.5pt)	+665.0%
Ordinary Income	6,393	+5,315	+492.9%
Net Income	5,019	+4,057	+422.2%
Depreciation	474	+66	+16.2%

Operating Income 6,038 (+5,249)

Cost of sales ratio (-3.1pt)

Decrease attributable to change in the sales mix

SGA Expenses (+766)

 Increase in R&D expenses due to progress in additional clinical study of SI-6603 in the U.S. (+266)

Ordinary Income 6,393 (+5,315)

Non-operating Income / Expenses (+65)

• Increase in foreign exchange gain (+100)

Net Income 5,019 (+4,057)

Income Taxes (+1,257)

• Higher income taxes due to the profit increase

Overview of Forecasts in FY2021

	FY2021	F	FY2020 Results*1		
(Millions of Yen)	Forecasts	Results	Change	% of Change	Degree of Progress
Net sales	32,200	27,734	+4,465	+16.1%	63.8%
Operating Income	4,550	2,248	+2,301	+102.3%	132.7%
Ordinary Income	4,650	3,024	+1,625	+53.7%	137.5%
Net Income	3,650	4,262	-612	-14.4%	137.5%
R&D Expenses (Ratio to net sales excluding royalty income)	7,900 (28.3%)	7,209 (26.7%)	+690 (+1.6pt)	+9.6%	48.1%
Average Exchange Rate (1US\$)	¥105.00	¥106.06			

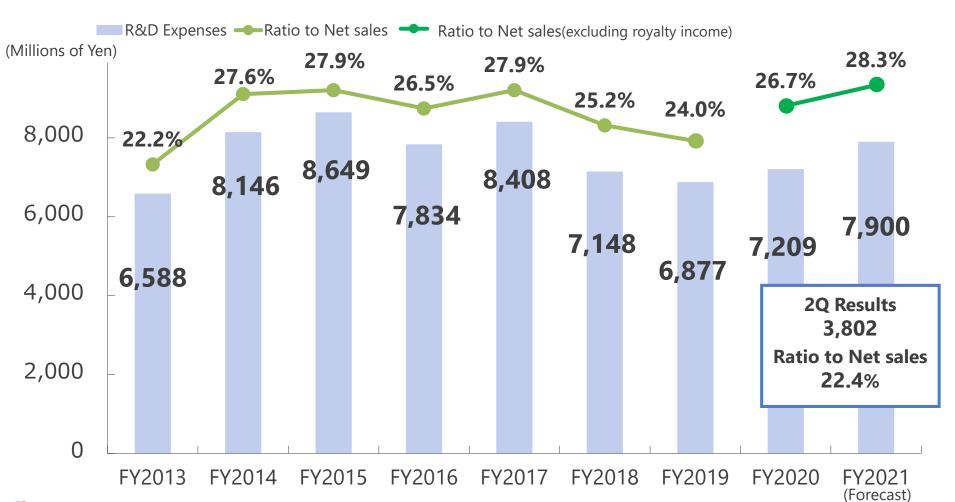
	FY2021 Forecasts	FY2020*1 Results
Net Income per share	¥64.83 ^{*2}	¥75.54
Dividend per share	¥30.00	¥24.00
Dividend Payout ratio	46.3%	31.8%

Exchange Rate Sensitivity (Impact of a change of ¥1against the US\$)				
Net sales Approx.¥150 million				
Operating income Approx. ¥60 million				

^{*1} It's corrected retrospectively in the new revenue recognition standard *2 Including the impact of the acquisition of treasury stock in July 2021 SEIKAGAKU CORPORATION

Trend in R&D Expenses

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

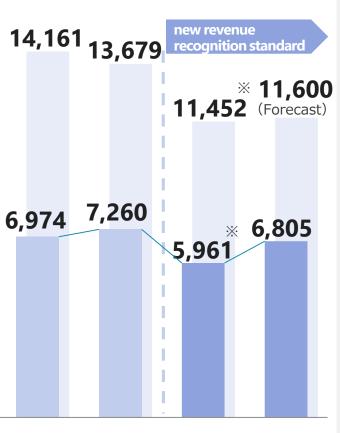


Domestic Pharmaceuticals 1/2 (Year-on-Year / Unit deliveries to medical institutions)

Domestic Pharmaceuticals Sales trend







'21.3

'22.3

'20.3

2Q FY2021 Results

+14.2% (Sales)

Impact of NHI drug price reductions offset by volume increase due to rebound from COVID-19 infection effects and JOYCLU launch

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

Market (+3.7%)

Trending toward recovery from COVID-19 infection impact

ARTZ (+6.3%)

2Q Results

 Volume and market share increased due to continuing effectiveness of measures to acquire new user facilities (62.3% / +1.6pt)

Forecasts

 Stronger demand due to promotion of switching from competing products

JOYCLU

2Q Results

Made ongoing efforts to provide information on appropriate use

Forecast

Expected to decrease significantly from initial forecast due to issuance of Blue Letter

'19.3

Safety Information on Joint Function Improving Agent JOYCLU

Blue Letter (rapid safety information) issued June 1 Prompt provision of information to alert healthcare professionals Launched systematic investigation of 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

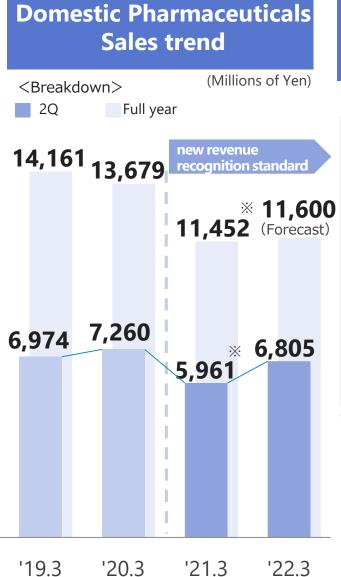
- To ensure patient safety by promptly alerting healthcare professionals of the situation to enable the provision of appropriate treatment and measures
- Addition of a WARNING section to the drug package insert and revision of the IMPORTANT PRECAUTIONS section
- Leaflet created to alert patients and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

In cooperation with Sales Partner Ono Pharmaceutical Co., Ltd. endeavoring to gather safety information and investigate cause We will continue to make efforts to provide safety information so that JOYCLU can be used appropriately

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)

Domestic Pharmaceuticals 2/2 (Year-on-Year / Unit deliveries to medical institutions)



2Q FY2021 Results

+14.2% (Sales)

Impact of NHI drug price reductions offset by volume increase due to rebound from COVID-19 infection effects and JOYCLU launch

Ophthalmic viscoelastic devices (Unit deliveries to medical institutions)

Market (+7.3%)

Surgery numbers recovering, but still below pre-COVID-19 levels

OPEGAN (+3.3%)

20 Results

- Volume increased due to market recovery
- Market share shrank, rebounding from volume increase due to shipment adjustments of competing products in same period of previous year (52.2% / -2.0pt)

Forecasts

• No change from start of fiscal year due to maintenance of newly acquired accounts

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

HERNICORE

20 Results

- Trending toward recovery from impact of COVID-19 infection
- Steady increase in the number of new user institutions

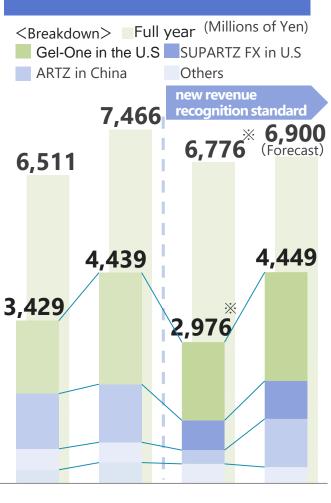
Forecasts

Working on market penetration, trending as earlier forecast



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

Overseas Pharmaceuticals Sales trend



2Q FY2021 Results +49.5%

In addition to rebound from COVID-19's impact in same period of previous year, sales up due to earlier-than-planned shipments of SUPART FX and of ARTZ in China

U.S.

* Foreign exchange impact: approx. +¥130million

Market in U.S.

- Trending toward recovery from impact of COVID-19 infection
- Continued preference for products that require low number of injections

Gel-One

2Q Results

(approx. +25% on a volume basis)

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

Seikagaku exports: Sales up due to increase in local sales volume

Forecast

Local sales: Slightly stronger demand due to more aggressive sales promotion activities

Seikagaku exports: Trending in line with initial forecast

SUPARTZ FX

2Q Results

Local sales: Increased due to recovery from impact of COVID-19 infection Seikagaku exports: In addition to increase in local sales, sales increased due to earlier-than-planned shipments

Forecast

Local sales: Trending in line with initial forecast

Seikagaku eports: Stronger demand due to earlier-than-planned shipments



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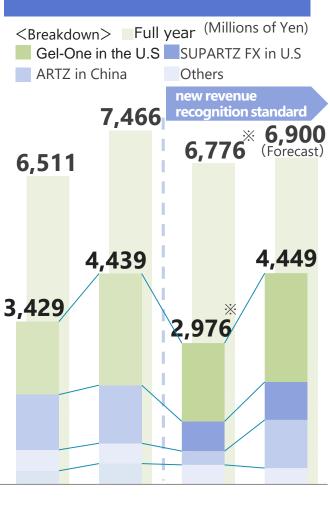
'203

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

Overseas Pharmaceuticals Sales trend



2Q FY2021 Results +49.5%

In addition to rebound from COVID-19's impact in same period of previous year, sales up due to earlier-than-planned shipments of SUPART FX and of ARTZ in China

* Foreign exchange impact: approx. +¥130million

China, Other Regions
Market in China

- Centralized purchasing by multiple provinces and districts commenced

• Following impact of COVID-19, has now returned to near normal

ARTZ in China

2Q Results

Local sales: Growth of successful bid areas for centralized purchasing, increased volume due to full-scale resumption of sales promotion activities

Seikagaku exports: In addition to increase in local sales volume, sales increased due to concentrated shipments in 2Q

Forecast

Local sales: Trending in line with initial forecast

Seikagaku exporsts: Strengthening due to concentration of shipment

timing, foreign exchange impact

Other Region

Seikagaku exports

2Q Results: Italy/Sales increased due to rebound from impact of COVID-19

Taiwan/Launched HyLink August 2021

Forecast: Italy / Weak



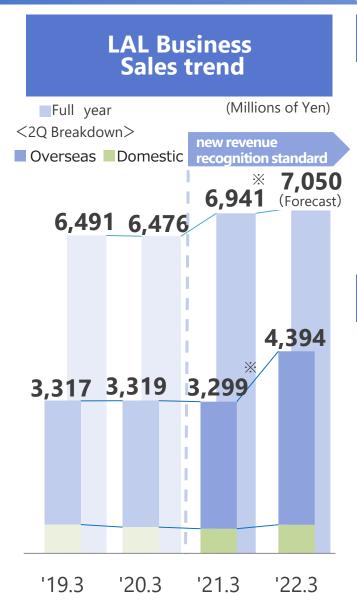
'19.3

'203

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'22.3

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



2Q FY2021 Results : +33.2% (Year-on-Year)

Overseas

* Foreign exchange impact: approx. - ¥20million

Growth in sales of Bacterial Endotoxin Testing (BET) and Clinical Diagnostic (Fungitell) reagents at overseas subsidiary

Domestic

Slight sales increase on solid sales of reagents and other products

FY2021 Forecasts

Overseas

Stronger demand due to enhanced sales promotion activities

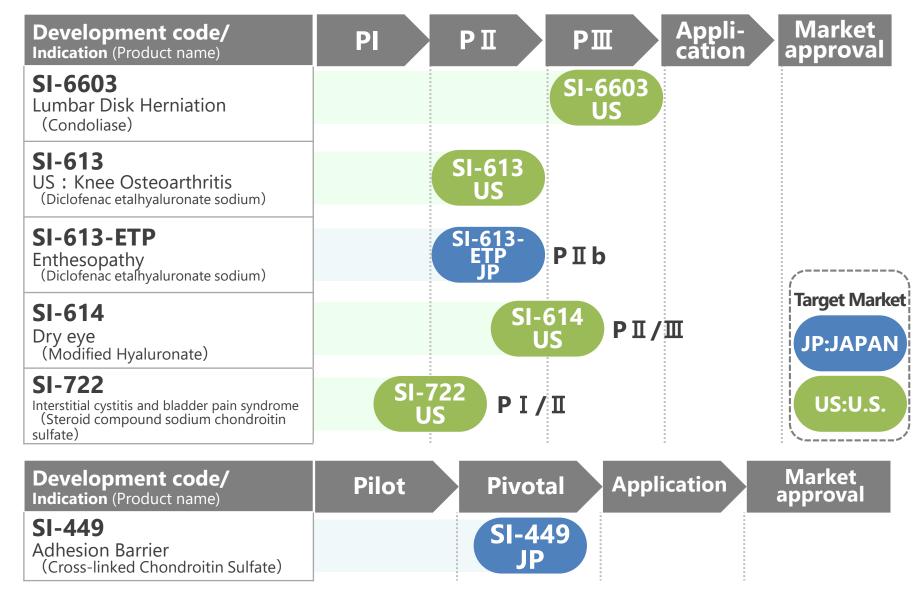
Domestic

Trending in line with initial forecast

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

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

Pipeline List (Research and Development themes)



SI-6603 (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. Aiming for November 2022 completion

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

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

⇒The measures have been successful, and the number of subjects enrolled has steadily increased

<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-613 (Osteoarthritis)

While scrutinizing JOYCLU situation in Japan, considering future development policy

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

► Future development policy under consideration

SI-613 (osteoarthritis of the knee) China

Agreement with Eisai on a co-development and marketing alliance in China, in April 2020
Future development policy under consideration

SI-613 (osteoarthritis of the knee) South Korea

► Agreement with Eisai for a market alliance in South Korea in September 2020 Future development policy under consideration

<SI-613 summary>

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

Indication : Osteoarthritis/Enthesopathy

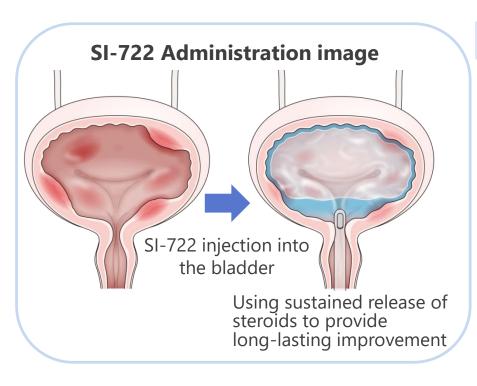
Method of use : Injection into joint cavity

Estimated patients: 24 million (U.S.) / 47 million (China) / 3.7 million (South Korea)

(Seikagaku estimates)

SI-722 (Interstitial cystitis and bladder pain syndrome)

Subject enrollment for PI/PII studies in the U.S. completed Advancing considerations for next-phase study



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

Promising features

- Designed for sustained release by bonding steroids to chondroitin sulfate
- ► Anti-inflammatory effects of steroids under sustained release should provide sustainable relief of frequent urination and bladder pain

<SI-722 summary>

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

Indication : Interstitial cystitis and bladder pain syndrome

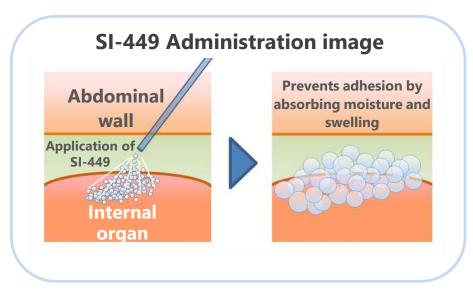
Method of use: Injection into the bladder

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



SI-449 (Adhesion Barrier / Medical Device)

Pivotal study started in May 2020 Significantly delayed due to COVID-19 infection



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



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Dividend of Surplus and Acquisition of Treasury Stocks

Dividend from Retained Earnings (Commemorative Dividend, Special Divided) Acquisition of Treasury Stocks

FY2020

Year-end dividend: Ordinary dividend ¥10 + JOYCUL approval commemorative dividend ¥4

Total ¥14 per share

→Annual dividend: ¥24 per share, including the interim dividend of ¥10 per share

FY2021

Ordinary dividend ¥20+ JOYCUL launch special dividend ¥10

→Annual dividend: ¥30 per share, including the interim dividend of ¥15 per share

	FY2017	FY2018	FY2019	FY2020	FY2021 (Forecast)
Net Income per share	¥69.30	¥39.76	¥-192.15	¥75.54	¥64.83 ^{※3}
Annual Total Dividend	¥26.00	¥26.00	¥26.00	¥24.00 ^{**1}	¥30.00 ^{**2}
Dividend Payout Ratio	37.5%	65.4%	_	31.8%	46.3%

X1 including a JOYCUL approval commemorative dividend ¥4

※2 including a JOYCUL launch special dividend ¥10

Acquisition of Treasury

*3 Including in the impact of the acquisition of treasury stock in July 2021

Total number of shares to be acquired: 200,000 shares (maximum)

Total amount of acquisition cost: ¥221,596,300 (maximum)

Acquisition period: July 1, 2021 to July 16, 2021

Appendix



Change in Accounting Standards

(Application of new revenue recognition standard, change in accounting classification of royalty income)

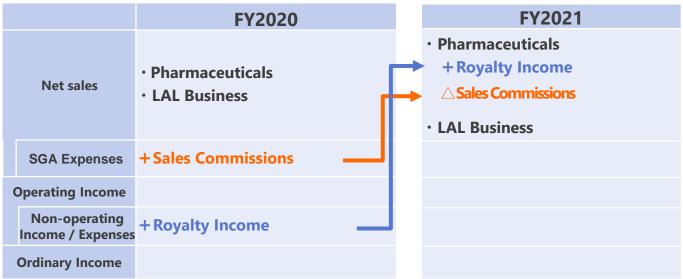
Change in accounting standards beginning from the first quarter of the fiscal year ending March 31, 2022

1. Application of a new revenue recognition standard

- Implementation of Accounting Standard for Revenue Recognition and its implementation guidance
- Reclassification of sales commissions paid to sales partners from SGA expenses to a sales deduction

2. Change in accounting classification of royalty income

- Revision of the sales and income recognition method to coincide with application of the new revenue recognition standard
- Royalty income, previously recognized as non-operating income, to be reclassified as net sales



Overview of Forecasts in FY2021

	FY2021	FY2020 Results * 1			
(Millions of Yen)	Forecasts	Results	Change	% of Change	
Net sales	32,200	27,734	+4,465	+16.1%	
Operating Income	4,550	2,248	+2,301	+102.3%	
Ordinary Income	4,650	3,024	+1,625	+53.7%	
Net Income	3,650	4,262	-612	-14.4%	
R&D Expenses (Ratio to net sales excluding royalty income)	7,900 (28.3%)	7,209 (26.7%)	+690 (+1.6pt)	+9.6%	
Average Exchange Rate (1US\$)	¥105.00	¥106.06			

	FY2021 Forecasts	FY2020*1 Results
Net Income per share	¥64.83 ^{*2}	¥75.54
Dividend per share	¥30.00	¥24.00
Dividend Payout ratio	46.3%	31.8%

Exchange Rate Sensitivity (Impact of a change of ¥1against the US\$)		
Net sales	Approx.¥150 million	
Operating income	Approx. ¥60 million	

^{*1} It's corrected retrospectively in the new revenue recognition standard *2 Including the impact of the acquisition of treasury stock in July 2021

* There is no change in forecast announced on May 13, 2021. 24

Forecasts (Net sales) in FY2021

	FY2021	Year-on-Year*	
(Millions of Yen)	Forecasts	Change	% of Change
Net sales	32,200	+4,465	+16.1%
Pharmaceuticals	25,150	+4,356	+21.0%
Domestic Pharmaceuticals	11,600	+147	+1.3%
Overseas Pharmaceuticals	6,900	+123	+1.8%
Bulk Products /CDMO	2,350	+503	+27.3%
Royalty income	4,300	+3,581	+498.8%
LAL Business	7,050	+108	+1.6%
(Overseas sales)	14,500	+856	+6.3%

Foreign exchange impact on overall net sales: approx. -50million yen * It's corrected retrospectively in the new revenue recognition standard

Net sales

- Forecast of higher sales from an increase in royalty income, the launch of the new product JOYCLU, and higher sales for bulk products/contract development and manufacturing, despite the negative impact of NHI price reductions
 - * Foreign exchange impact on overall net sales: approx. -50million yen

Pharmaceuticals

Domestic Pharmaceuticals

Sales at prior-year level, with the launch of JOYCLU offsetting the negative impact of NHI drug price reductions

Overseas Pharmaceuticals:

Sales increase from higher local sales volumes of Gel-One and ARTZ in China

Bulk Products/CDMO:

Sales increase from contract development and manufacturing (Dalton)

Royalty income:

Projected increase in royalty income

LAL Business

Projected increase in royalty income

* There is no change in forecast announced on May 13, 2021. ²⁵



Forecasts (Income) in FY2021

	FY2021	Year-on-Year *	
(Millions of Yen)	Forecasts	Change	% of Change
Net sales	32,200	+4,465	+16.1%
OperatingIncome (Ratio to net sales)	4,550 (16.3%)	+2,301 (+8.0pt)	+102.3%
Ordinary Income	4,650	+1,625	+53.7%
Net Income	3,650	-612	-14.4%
Cost of Sales ratio (excluding royalty income)	38.8 % (44.8%)	-4.9 _{pt} (±0.0 _{pt})	-
R&D Expenses	7,900	+690	+9.6%
R&D Expenses ratio (excluding royalty income)	24.5 % (28.3%)	-1.5 _{pt} (+1.6pt)	_
Depreciation	1,150	+341	+42.2%

^{*} It's corrected retrospectively in the new revenue recognition standard

Operating Income

SGA Expenses (approx. +1,700):

- Increase in R&D expenses (+690)
- JOYCLU post-marketing surveillance, higher subsidiary expenses

Ordinary Income

Non-operating Income / Expenses:

• Projected increase in foreign exchange loss

Net Income

Income Taxes

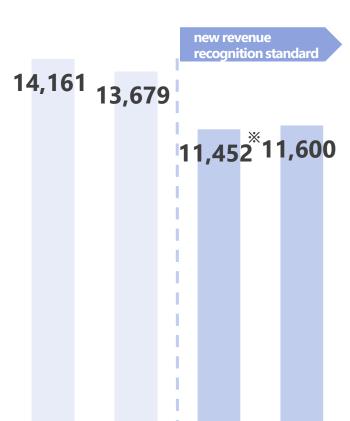
 Recognition of deferred income taxes in connection with recognition of deferred tax assets in the prior-year period (-1,561)

Domestic Pharmaceuticals (FY2021 Forecast Year-on-Year / Unit deliveries to medical institutions)



(Millions of Yen)

FY2021



+1.3%

(sales basis)

Sales at prior-year level, with the launch of JOYCLU offsetting the negative impact of NHI drug price reductions

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

Market

• Projected continuation of the downtrend in outpatient services

ARTZ

 Forecasting a year-on-year decrease due in part to continued impact of COVID-19

JOYCLU

• Aiming for early market penetration through appropriate information provision

Ophthalmic viscoelastic devices (Unit deliveries to medical institutions)

Market

• Number of surgeries expected to remain at the low prior-year level

OPEGAN

 Forecasting a decrease due to resumption of shipments of competing products

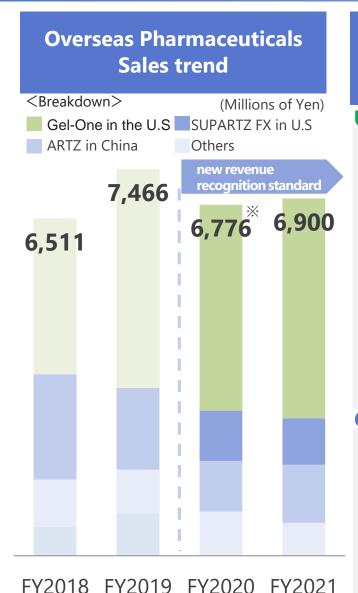
Treatment for lumbar disc herniation (Unit deliveries to medical institutions)

HERNICORE

 Deliveries at the prior-year level projected due to growth in the number of new user institutions, despite continuation of the downtrend in outpatient services

FY2018 FY2019 FY2020

Overseas Pharmaceuticals (FY2021 Forecast Year-on-Year / value basis)



FY2021 Forecast +1.8%

The impact of COVID-19 expected to run its course, and sales projected to increase on higher volumes

U.S.

Market in the U.S.

Projected market recovery trend, with impact of COVID-19 running its course

Sales in the U.S.

Gel-One: Forecasting a local sales increase due to

strengthening of sales promotion activities

SUPARTZ FX: Forecasting a decrease due to continuation of the trend favoring products that require a low number of injections

Seikagaku exports

Gel-One exports projected to rise due to the local sales increase/ SUPARTZ FX exports projected to fall due to the local volume decrease

China, Other Regions

Local sales of ARTZ in China

Forecasting a sales increase to result from maintenance of the current level of sales to large urban hospitals and opening up of the mid-size hospital market

▶ Seikagaku exports

ARTZ exports to China projected to rise due to a local sales increase No recovery from the impact of COVID-19 in Italy expected, and exports projected to be at the prior-year level



 \ast It's corrected retrospectively in the new revenue recognition standard

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

Recombinant LAL reagent 「PyroSmart NextGen™」

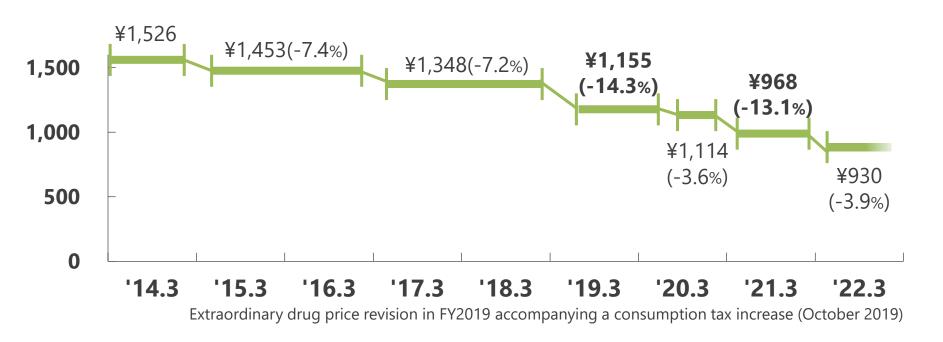
April 2021 launch at ACC Product to be marketed globally, with a launch in Japan planned for May or later in 2021

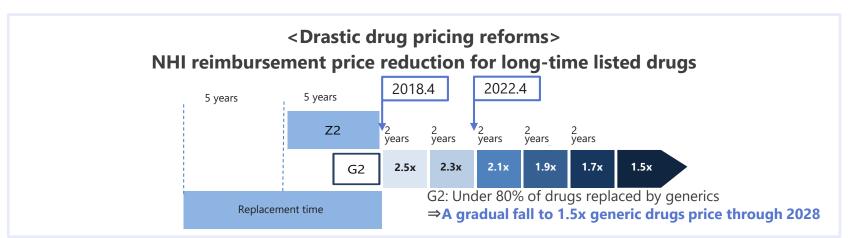


Product Features

- ▶ 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

Trend in NHI Reimbursement Price of ARTZ to Domestic





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



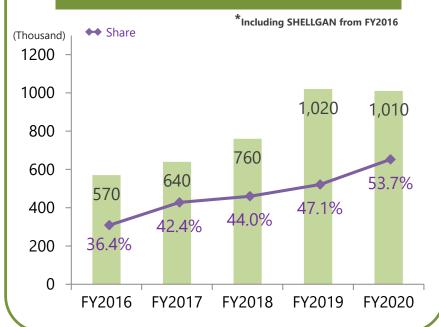
Ophthalmic viscoelastic devices

OPEGAN



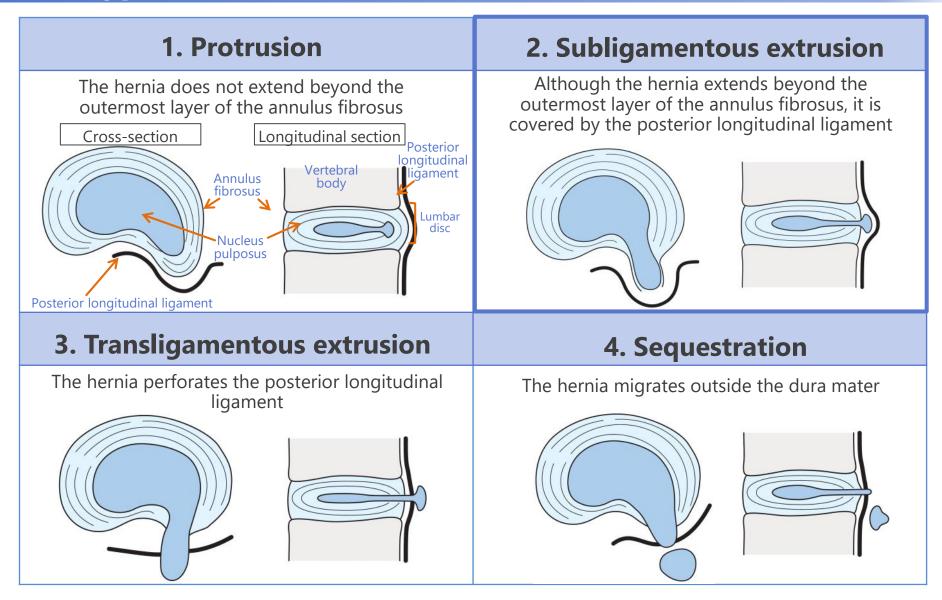
- The first domestically HA formulation
- Used in cataract surgery to anterior chamber expansion
- Distributor: Santen Pharmaceutical

Trend in unit deliveries to medical institutions



EIKAGAKU CORPORATION

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





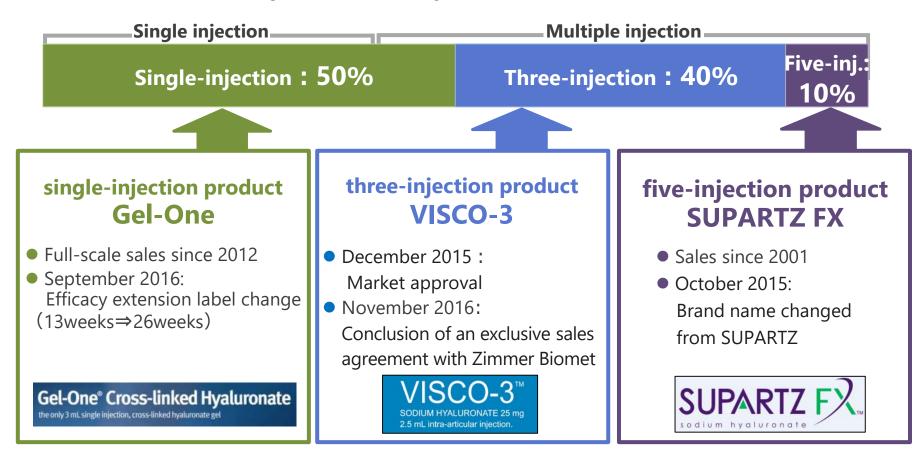
The OPEGAN series, used mainly in cataract surgery

The OPEGAN family viscoelasticity comparison

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

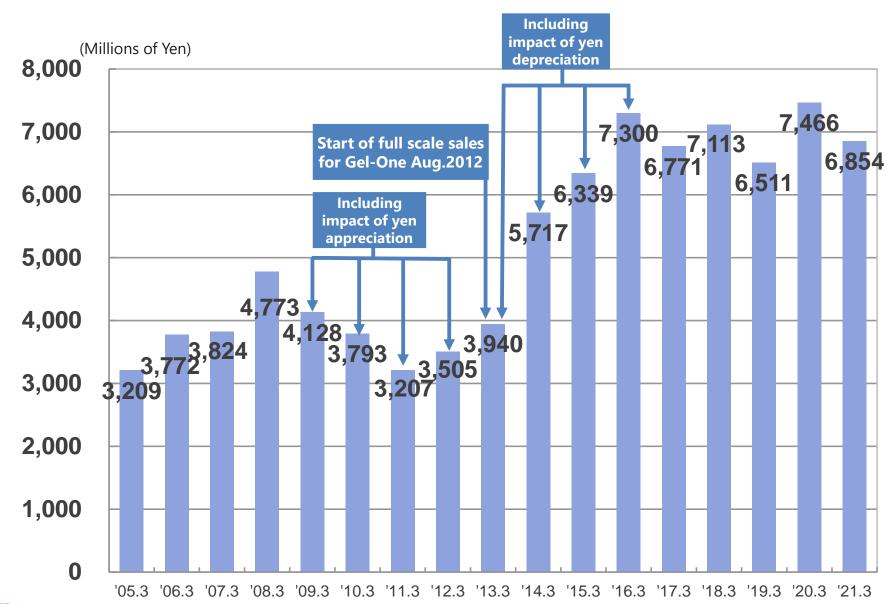
Market size of US\$800 mil. in 2020 (-15.0% year-on-year)

■ 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



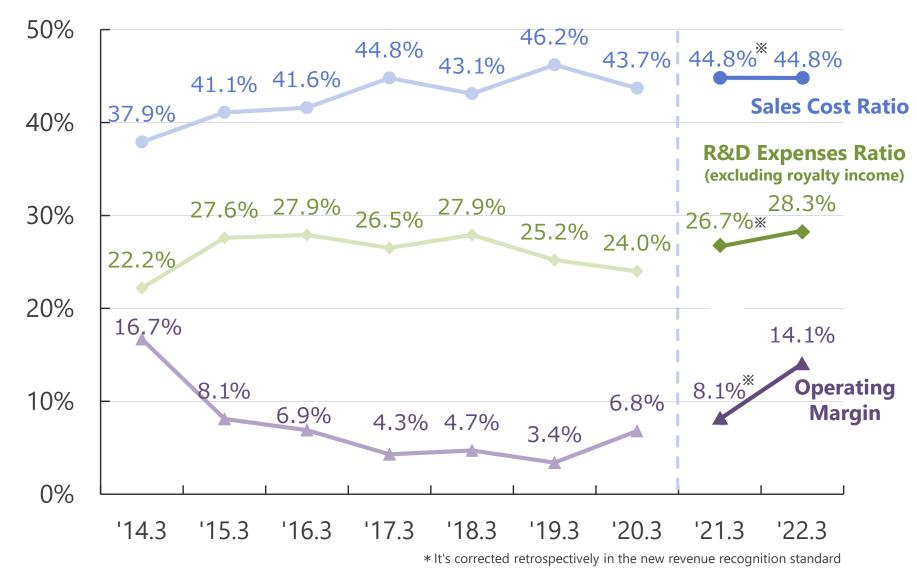
Endotoxin detection reagents (for quality control of pharmaceuticals and medical devices)



PYROCHROME®



Trend in Financial Index

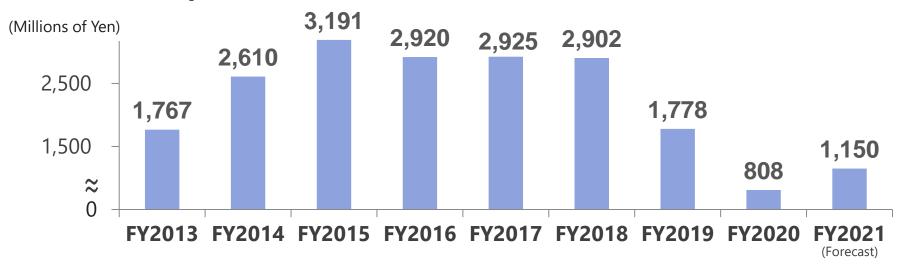




Trends in Depreciation & Capital Investments

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

Trend in Depreciation

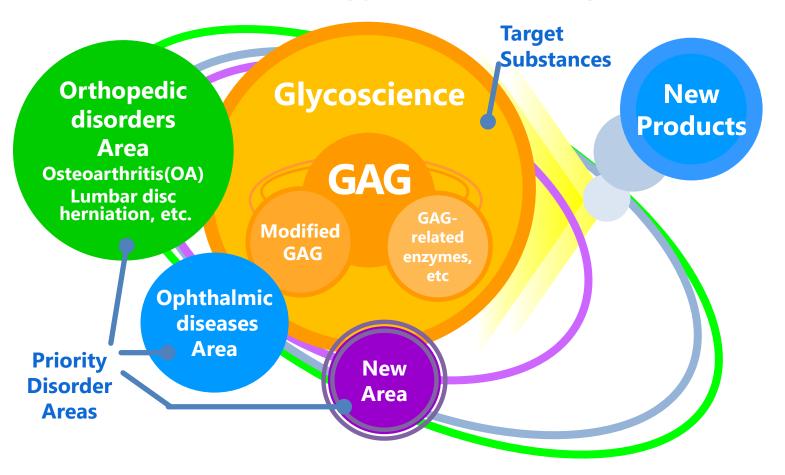


Trend in Capital Investments (Millions of Yen)

FY2013	FY2014	FY2015	FY2016	FY2017	FY2018	FY2019	FY2020	FY2021 (Forecast)
7,222	2,095	1,975	1,173	1,591	1,310	2,109	2,127	3,000

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

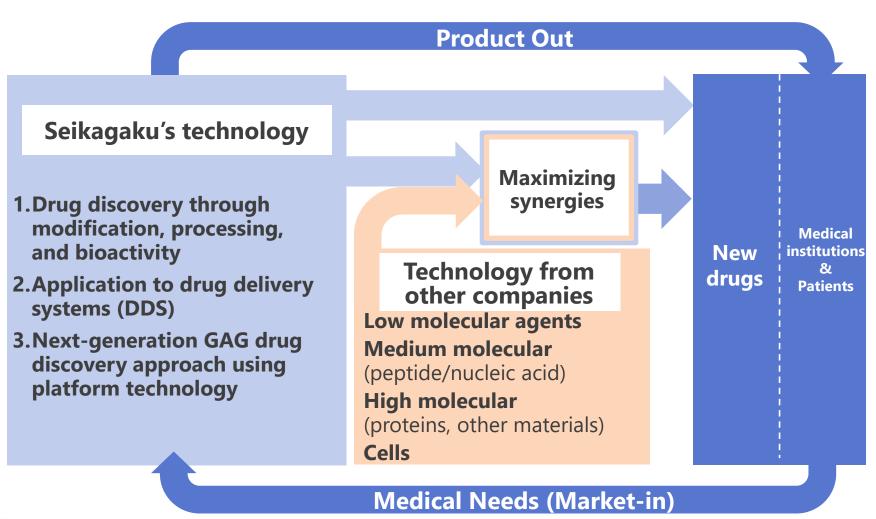
- Conversion from natural GAG to fermented GAG
- Expanding the field of sugar chain drug discovery Applying to glycobiology

SI-613 SI-614



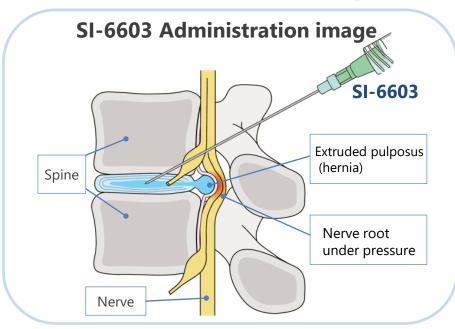
Accelerating Innovative Drug Discovery Using The Open Innovation Strategy

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)

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

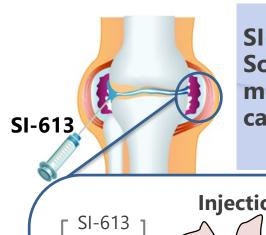
Method of use : Injection into joint cavity

Estimated patients: 24 million (U.S.) / 47 million (China) / 3.7 million (South Korea)

(Seikagaku estimates)

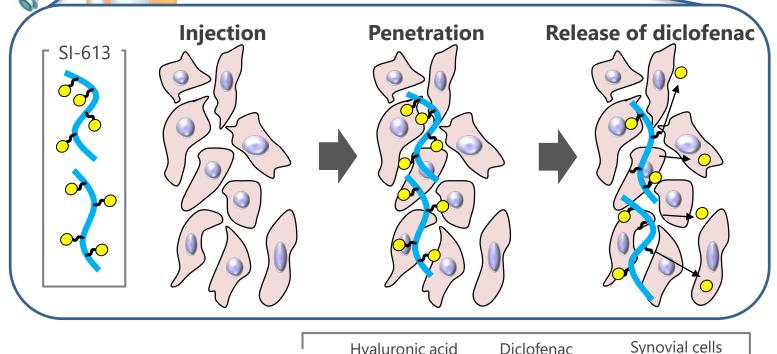


Sustained Release of Diclofenac in SI-613



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

Diclofenac



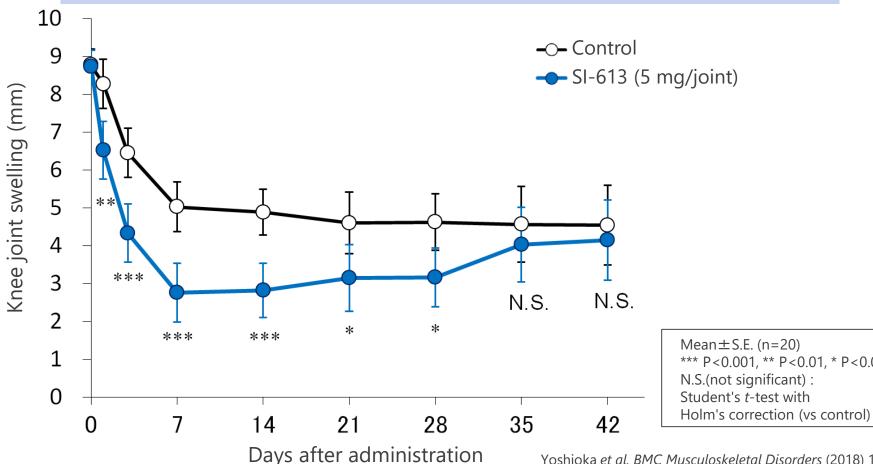
Hyaluronic acid

Legend



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

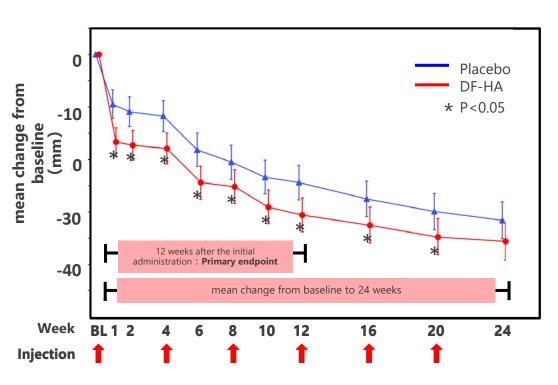


*** P<0.001, ** P<0.01, * P<0.05

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

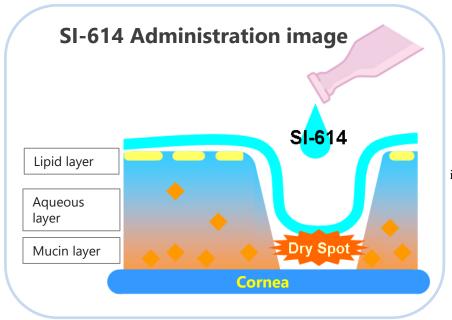
Main Secondary endpoints: WOMAC stiffness score and physical function score
Statistically significant difference found versus the placebo group in difference in mean change in WOMAC scores from baseline to 12 weeks after initial administration

Safety evaluation:

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

SI-614 (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-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 (<u>JapicCTI-205343</u>)	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)	
	Japan	Ono Pharmaceutical Co., Ltd.	Max. ¥12.0 billion (¥2.0 billion)	
SI-613	U.S.	Searching	_	
Japan: Osteoarthritis U.S.: Knee Osteoarthritis	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	_	_	

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





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

Basic policy on profit distributions

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



Shareholder returns

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

Business investment

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

Strategic investment

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

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

Seikagaku's vision

Our vision

A company that is valued by the world through its innovative drug discovery

Core values (motto)

Creativity, Fairness, Dreams and Passion

Creed

We create safe and useful products for human well-being with basic research based on glycoscience.

Guidelines for Our Activities

- We create a corporate environment of mutual trust and communication using individual abilities.
- We create innovative and useful products through in-depth cooperation between industrial and academic circles.
- We assure the highest quality and safety of our products.
- We enhance interaction with society by establishing genuine trust.
 Through these efforts, Seikagaku will strive to become a sound and socially responsible company that protects the natural environment and improves quality of life.

Mission statement

"Glycoscience for human well-being"

Corporate slogan of the new mid-term management plan

"Innovative Thinking"
Creating value based on innovative thinking

Special Profile



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

.........

74.9%

Domestic Pharmaceuticals

→ 43.4%

Joint Function Improving Agents



Overseas
Pharmaceuticals

→ 24.8%



Net Sales

27,662 million

(FY2020 Results)

Ophthalmic Surgical Aids



Bulk Products



Bulk Products/ CDMO

⇒ 6.7%



LAL Business 25.1%



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.



