Exploring the Innovative Promise of Glycoscience

Financial Results for the 2nd Quarter of Fiscal Year 2026

(April 1, 2026 – September 30, 2026)

SEIKAGAKU CORPORATION

(TSE：4548)

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2Q of FY2026 Results

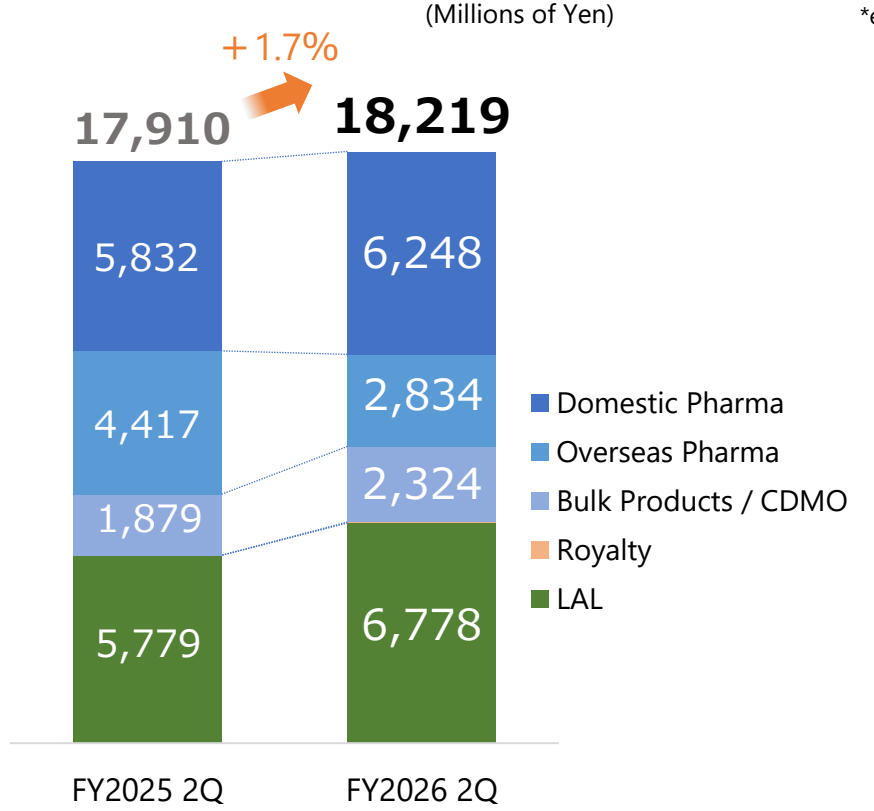
Overview for 2Q of FY2026

- Net sales: Up 1.7% year on year on higher sales of domestic pharmaceuticals and from the LAL business, despite lower sales of overseas pharmaceuticals.
- Income: Operating loss of ¥1,415 million was recorded due to increases in manufacturing costs and R&D expenses. Ordinary income of ¥602 million was recorded due in part to sales of investment securities, while a net loss of ¥1,221 million was recorded due to an increase in tax expenses resulting from the reversal of deferred tax assets.
- Full-year consolidated results forecast revised in light of the recent trend of business results.

(Millions of Yen)	2Q FY2025 Results	**2Q FY2026 Results**	% of Change
Net Sales	17,910	**18,219**	+1.7%
Operating Income	-557	**-1,415**	—%
Ordinary Income	531	**602**	+13.4%
Net Income	229	**-1,221**	—%
Net Income per Share	¥4.21	**-¥22.36**	—

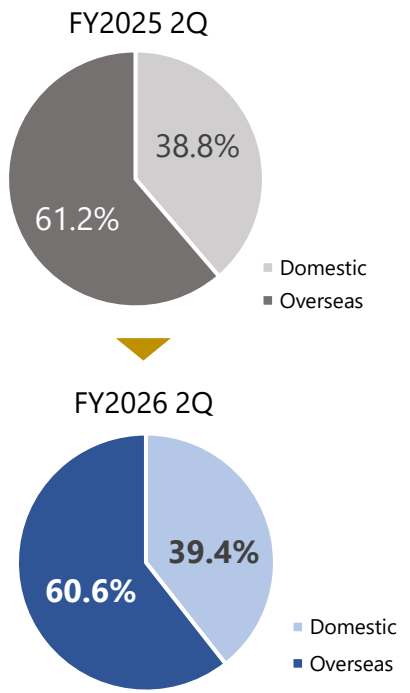
Other Performance Indicators	FY2025 2Q	**FY2026 2Q**	% of Change
R&D Expenses (Millions of Yen)	3,027	**3,337**	+10.2%
Ratio of R&D expenses to sales (excluding royalty income)	16.9%	**18.4%**	+1.5Pt
Ave. exchange rate during the period (1USD)	¥146.0	¥159.4	+¥13.4

Net Sales by Business Segment



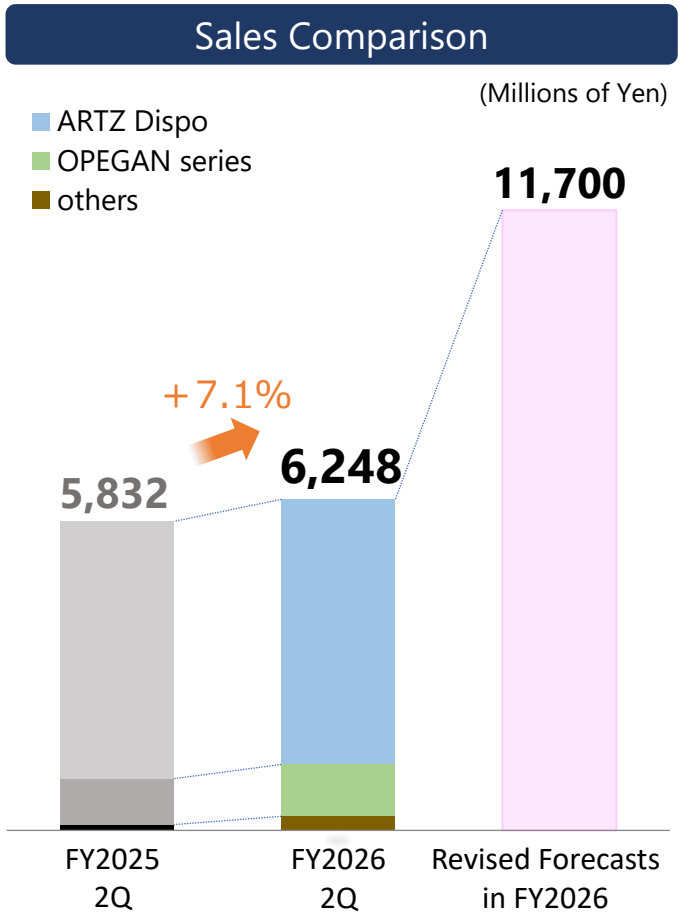
Overseas Sales Ratio

*excluding royalty income



Domestic Pharmaceuticals

➢ Net sales up 7.1% year on year due to higher shipment volumes of ARTZ and the OPEGAN series.



ARTZ（Joint-function improving agent）

◆Market environment:

・Although the population is aging, treatment options for osteoarthritis are becoming more diversified, and the market for intra-articular hyaluronic acid injections is flat*.

・Top share maintained. (approx. 80%*)
Maintaining trust by leveraging status as an original drug through appropriate provision of information to medical institutions together with the sales partner.
Continuous holding of seminars at academic conferences.

◆Seikagaku sales: Up year on year due to higher shipment volumes.

OPEGAN series（Ophthalmic viscoelastic devices）

◆Market environment:

・Because of use mainly for cataract surgery, market expansion trend accompanying growth in the elderly population*.

・Top share maintained. (approx. 50%*)
Pursuit of further market penetration in cooperation with the sales partner.

◆Seikagaku sales: Up year on year due to higher shipment volumes.

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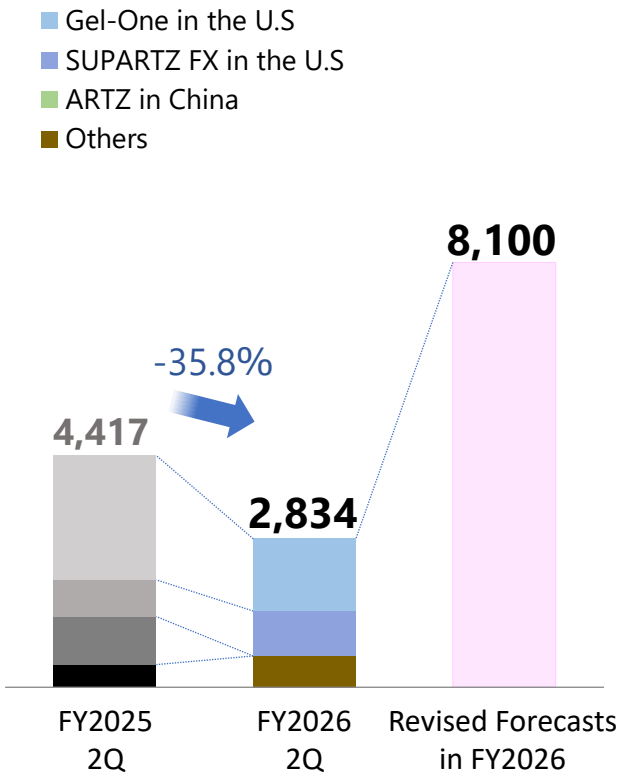
Overseas Pharmaceuticals

➢ Net sales down 35.8% year on year due to lower sales of Gel-One for the U.S. and ARTZ for China.

Sales Comparison

(Millions of Yen)



Products for the U.S.

◆Market environment:

- Although the number of patients is increasing, market expansion on a value basis is limited due to intensifying price competition.
- Single-injection and 2-5 multiple injection products available, with single-injection products making up about half the total market.
- Seikagaku continue sales promotion activities appropriate for each product, gazing the trend of competing products.

◆Seikagaku sales:

Sales down on lower sales of Gel-One (single-injection viscosupplement) due to shipment timing.

ARTZ in China

◆Market environment:

- Despite gradual market growth against the backdrop of expansion of the elderly population, future trend difficult to forecast due to expansion of the centralized procurement system by the national government and provinces.
- Appropriately providing information to medical institutions and at relevant academic conferences and continuing activities to expanded sales while earning trust as an original product.

◆Seikagaku sales:

Shipments paused because of procedures for a changeover of materials. Shipments scheduled to resume from 3Q.

Foreign exchange impact: +183 million yen

Bulk Products / CDMO, Royalty, LAL Business

Bulk Products / CDMO

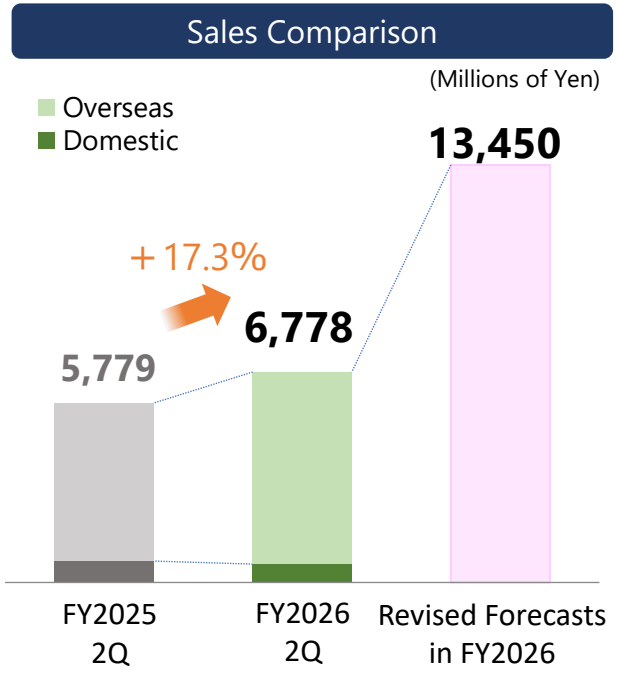
- Net Sales: 2,324 million yen (Up 23.7% year on year, Foreign exchange impact: +165 million yen)
- Seikagaku sales increased mainly in contract development and manufacturing services.

Royalties

- Net Sales: 33 million yen (1 million yen in the same period of the previous year)

LAL Business

- Sales up 17.3% year on year due to strong overseas sales.



Foreign exchange impact: +390 million yen

◆Market environment:

・Endotoxin-detecting reagents
Used mainly for quality control in pharmaceutical manufacturing processes.
Stable growth is expected from both conventional products derived from horseshoe crab blood and products manufactured using non-animal-derived raw materials, including Pyrosmart NextGen (PSNG).

・Beta-glucan-detecting in vitro reagent
Used mainly as a diagnostic for deep fungal infections.
Sales growing, mainly in the U.S. Increased the number of countries where the products is sold and expand the product range with further growth forecast.

◆Seikagaku sales:

Sales up 17.3% year on year due to strong overseas sales of endotoxin-detecting reagents and Fungitell (a beta-glucan-detecting in vitro diagnostic).

Summary of Revised Consolidated Earnings Forecast and Dividend Forecast for FY2026

- Net sales: No change from the forecast announced on September 24, 2026.
- Income: The earnings decline is expected to widen due to newly estimated expenses related to preparations for the resubmission of SI-6603.
- Dividend Forecast:
  Taking into account recent business performance, financial condition, the future business environment, and funding requirements for business development, the Company revised its annual dividend forecast to ¥20.00 per share on September 24, 2026.

[Full-Year Consolidated Earnings Forecast]

(Millions of Yen)	Previous Forecasts(A) (Announced: Sep. 24)	**Revised Forecasts(B) (Announced: Nov. 10)**	Change (B-A)
Net Sales	37,100	**37,100**	—
Operating Income	-2,050	**-2,900**	-850
Ordinary Income	200	**-650**	-850
Net Income	-1,800	**-2,700**	-900
Net Income per Share	-¥32.96	**-¥49.43**	—

Assumed exchange rate remain unchanged from the initial forecast (¥155/USD).

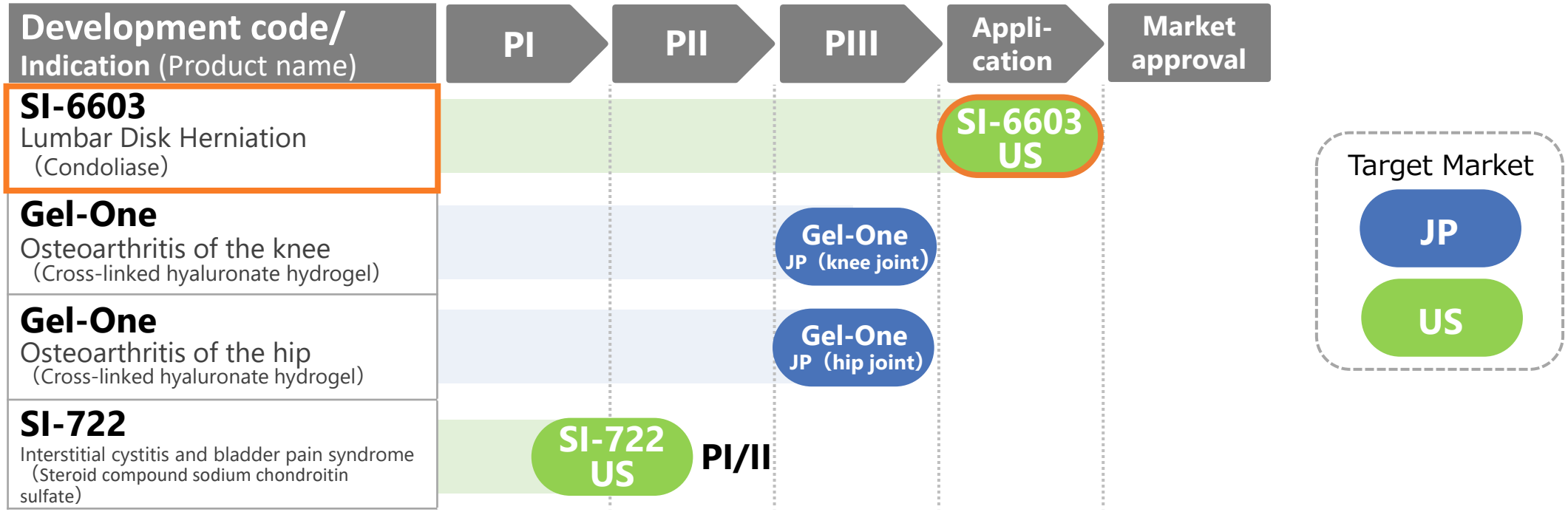
[Dividend Forecast]

(per share)	Initial Forecasts	**Revised Forecasts (Announced: Sep. 24)**
Interim	¥15	**¥10**
Year-end	¥15	**¥10**
Annual	¥30	**¥20**

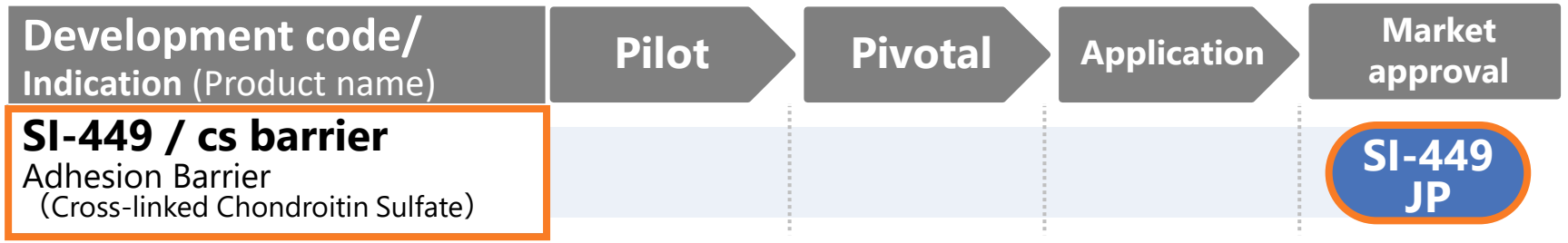
Research and Development

Pipeline List

<Pharmaceuticals>



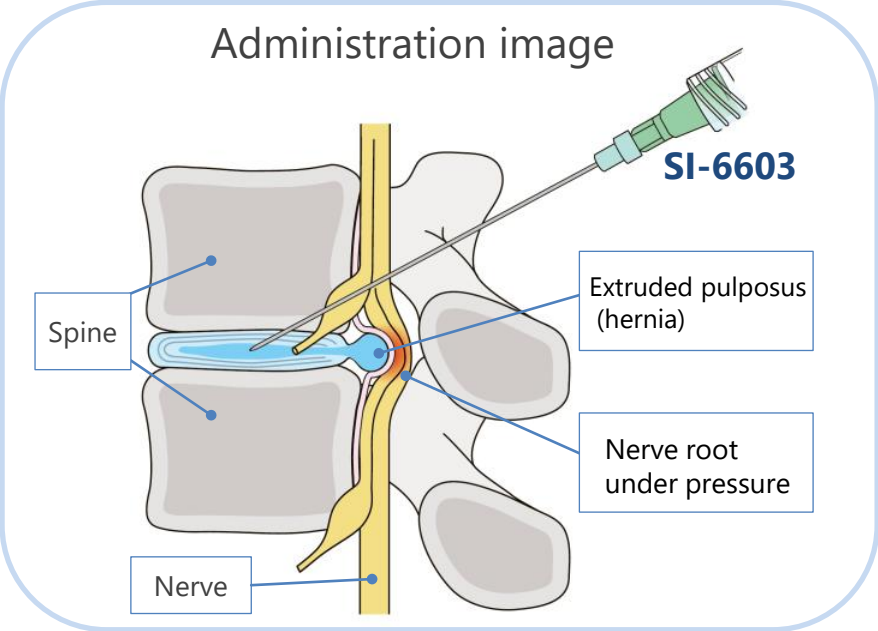
<Medical Device>



: SI-6603 Complete Response Letter received from the U.S. Food and Drug Administration (Sep. 2026)
: SI-449 Marketing approval as a medical device obtained (Apr. 2026)

SI-6603 (Treatment for Lumbar Disc Herniation)

- Complete response letter (CRL) from the U.S. Food and Drug Administration (FDA) received in Sept. 2026 indicating non-approval.
- Although at this time, resubmission is expected to take approximately 1 to 1.5 years from the receipt of the CRL, this is subject to change since some observations were made at the contract manufacturing facility.



Development status

▶Sept. 2026: CRL received from the U.S. FDA (non-approval)

- The following two observations were cited as reasons for non-approval:
  1) The FDA determined that deficiencies identified during the inspection of the drug substance manufacturing facility had not been fully addressed.
  2) Deficiencies were identified during cGMP inspection at the contract manufacturing facility for the drug product.

Expected Features

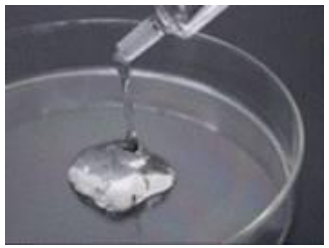
▶Relieving symptoms by decreasing intradiscal pressure and reducing the pressure on the nerve root by single injection.

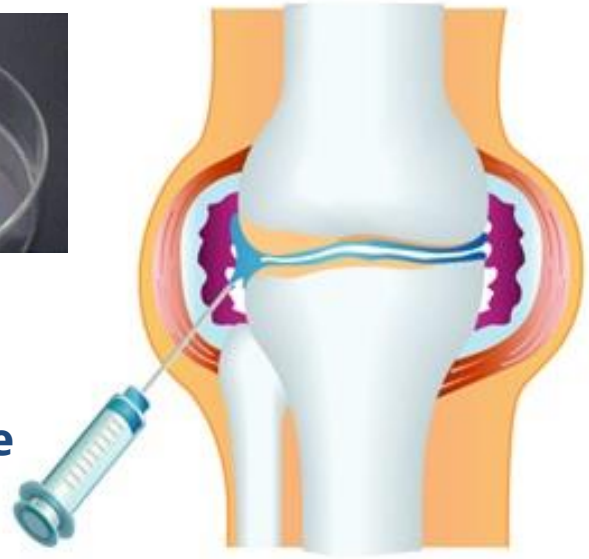
▶It can be administered without general anesthesia, and the administration can be less invasive for the patient compared to surgical technique because of direct intradiscal injection.

<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)
New patients with lumbar disc herniation：3 to 5 million per year (Seikagaku estimates)

Gel-One（Osteoarthritis of the knee and hip）

- Intra-articular injection whose main ingredient is a cross-linked hyaluronate hydrogel made using Seikagaku's unique cross-linking technology.
- Phase III clinical trials are underway in Japan and progressing steadily.





Gel-One

Development status

▶ **Phase III studies in Japan**

- Initiated Phase III clinical studies of the knee joint and hip joint in February 2025.
- Conclusion of an agreement on joint development and sales partnership with Ono Pharmaceutical Co., Ltd. In August 2025.

Expected Features

▶ Designed to remain in the local joint environment for a long time after injection in the knee joint cavity, with pain reduction from a single injection confirmed in U.S. clinical studies.

▶ At this time, no other hyaluronic acid monotherapy is indicated for osteoarthritis.

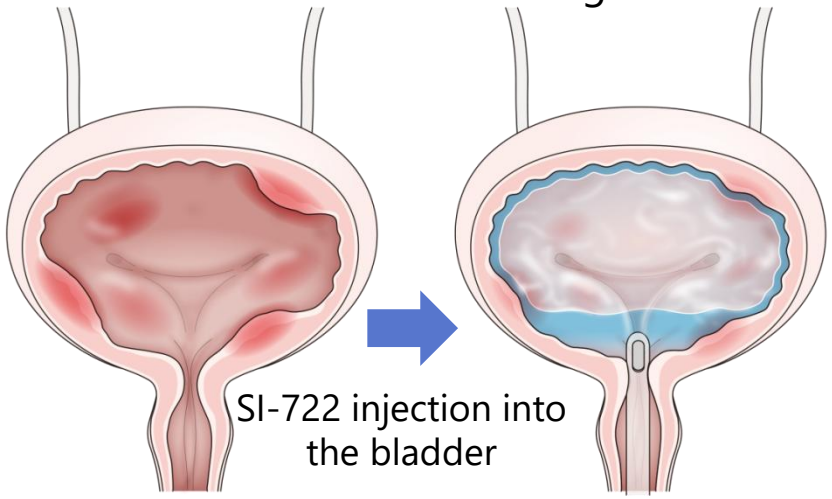
＜Gel-One summary＞
Dev. Code：Gel-One ／ Generic name：Cross-linked hyaluronate hydrogel
Indication：Osteoarthritis of the knee and the hip／ Method of use：Injection into the joint cavity
Estimated Japan patients：Osteoarthritis of the knee　Approx. 8 million*1、Osteoarthritis of the hip　1.2 to 5.1 million (prevalence rate of 1.0% to 4.3%*2 extrapolated to the population of Japan)

*1：Clinical Practice Guidelines for the Management of Knee Osteoarthritis 2023
*2：Clinical Practice Guidelines for the Management of hip Osteoarthritis

SI-722 (Interstitial cystitis and bladder pain syndrome)

➢ Phase I/II clinical studies in the U.S. completed. Currently considering the future development policy.

Administration image



Development status

▶ **Phase I/II studies in the U.S. Completed**

・Subject enrollment complete in January 2021, and tolerability confirmed. (a primary objective)

Expected Features

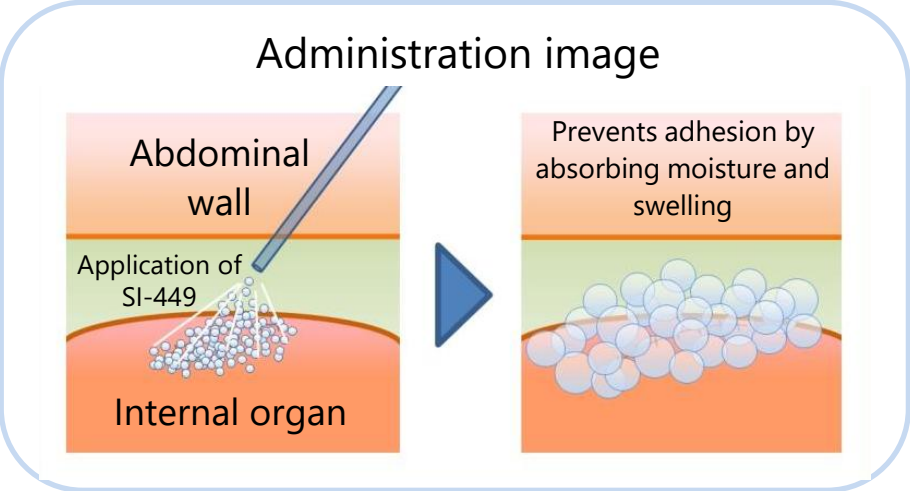
▶ Designed for sustained release by bonding steroids to chondroitin sulfate.

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

＜SI-722 summary＞
Dev. Code：SI-722 ／ Generic name：Steroid conjugated with chondroitin sulfate
Indication：Interstitial cystitis and bladder pain syndrome ／ Method of use：Injection into the bladder
Estimated U.S. patients ：1.3 million (Seikagaku estimates)

SI-449 / cs barrier (Adhesion Barrier / Medical Device)

- An insurance reimbursement price of ¥34,100 per gram was decided.
- Scheduled to be included in insurance coverage in December 2026.
- Will proceed with preparations for market introduction together with the sales partner (Covidien Japan, Inc.).



Development status

▶ **marketing approval for a medical device in Japan**

・Obtained marketing approval for a medical device in April 2026.
(Product Name: "cs barrier® ")

・Sept. 2026: Insurance reimbursement price of ¥34,100/g decided

▶ **Proceed with development with a view to global development.**

Expected Features

▶ A powdered adhesion barrier agent primarily composed of cross-linked chondroitin sulfate created using our own glycosaminoglycan cross-linking technology.

▶ 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)

Other Topics

Status of Application for Approval of SI-6603 in the United States

Timeline

- March 2024: Approval application submitted to the U.S. Food and Drug Administration (FDA)
- January 2025: Holding of Advisory Committee Meeting, an FDA examination process. SI-6603 risks and benefits discussed, and broad support for approval obtained
- March 2025: Complete Response Letter(CRL) received from FDA. SI-6603 not approved
- March 2026: Responded to observations and resubmitted an approval application to the FDA.
- September 2026: Received a CRL from the FDA indicating non-approval.

CRL Content

- Observations were made about the following two points.
  1) The FDA determined that deficiencies identified during the inspection of the drug substance manufacturing facility had not been fully addressed.
  2) Deficiencies were identified during cGMP inspection at the contract manufacturing facility for the drug product.
- Although the number of observations about Seikagaku decreased from the previous review, observations about the external manufacturing facility were added.
- No concerns relating to the clinical study results, including efficacy and safety, expressed.

Future Outlook

- Seikagaku will consider the timing of resubmission in closer collaboration with licensee Ferring Pharmaceuticals.
- Resubmission is expected to take approximately 1 to 1.5 years from the receipt of the CRL.
- However, the projected timeline is subject to change depending on the response of the contract manufacturing facility.

Appendix

Main products and Key Alliances with Companies in Japan and Overseas (Including Products under Development)

➢ Seikagaku has product and R&D operations in Japan, the United States, China, Taiwan, and Italy.

Joint function improving agent/Treatment of osteoarthritis

- ARTZ Dispo (Japan, Taiwan)
- JOYCLU (Japan)
- Gel-One (Products under Development: Japan)
- ARTZ (China)
- HyLink (Taiwan, Italy)
- Gel-One (U.S.)
- SUPARTZ FX (U.S.)
- VISCO-3 (U.S.)

Ophthalmic viscoelastic device

- OPEGAN series (Japan)

Treatment for lumbar disc herniation

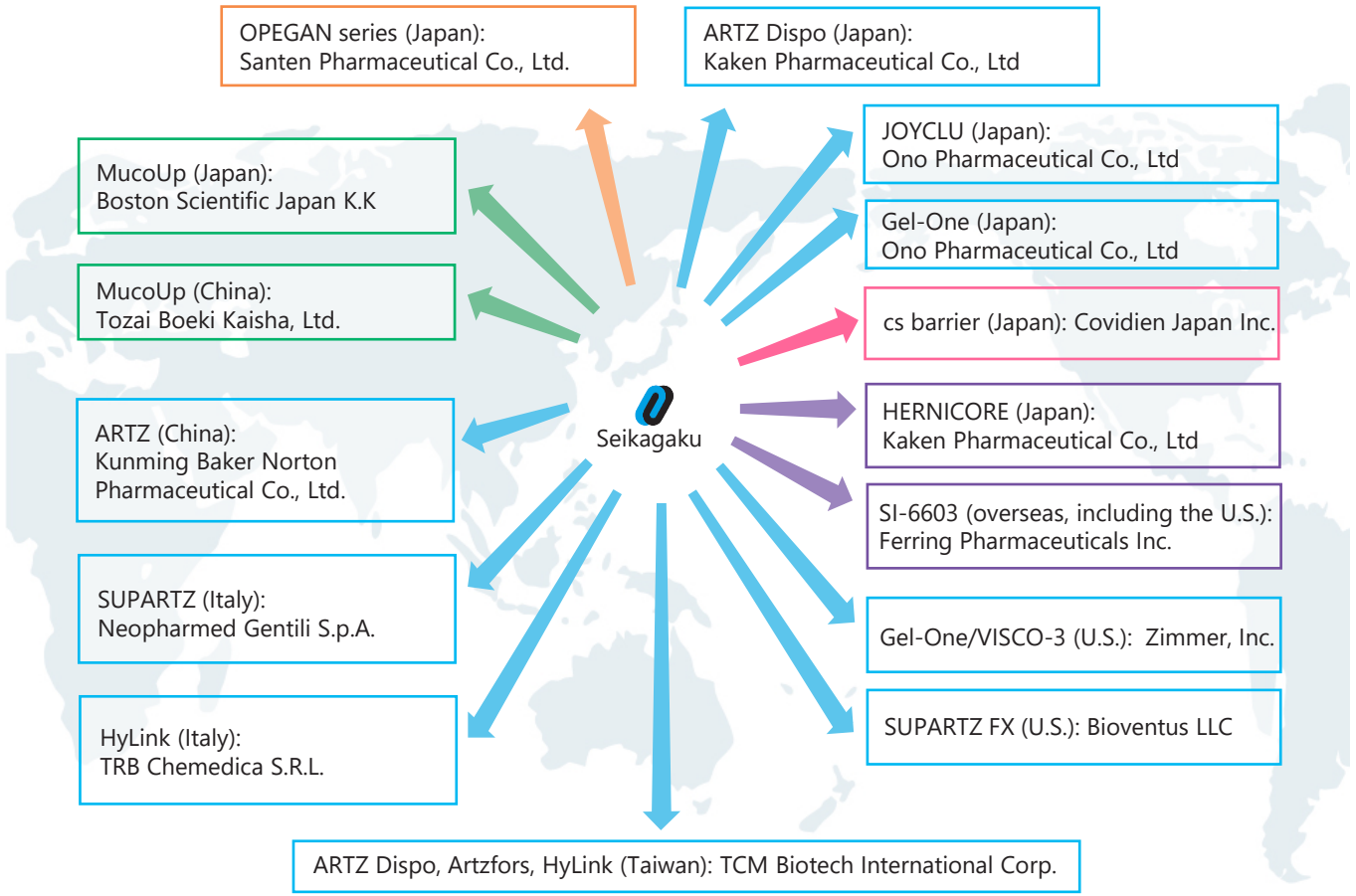
- HERNICORE (Japan)
- SI-6603 (Products under Development: U.S.)

Surgical aid for endoscopic mucosal resection

- MucoUp (Japan, China)

Adhesion Barrier

- cs barrier (Products under Development: Japan)



As of June 30, 2026

■Cautionary Notes

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

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