GNI Group Ltd.

Q1 FY2026 Financial Results Presentation

We Bring New Hope to Life

Securities Code: TSE:2160

Agenda

1. Company Overview
2. Q1 FY2026 Segment Results
3. Q1 FY2026 Financial Highlights
4. Supplementary Materials

1. Company Overview

Director, Representative Executive Officer, President, and CEO

Ying Luo Ph.D.

To develop new treatments for unmet medical needs, He is leveraging the unique strengths of the pharmaceutical industries in Japan, the U.S., and the PRC, and pioneering a new, highly profitable business model.

He obtained a Ph.D. in Molecular Biology/Biomedical Sciences from the University of Connecticut Health Center in 1991. He has co-authored over 40 research studies and publications and is an inventor on over 16 patents during his 30+ years of biotech career.

Developed our Group's flagship product, ETUARY™ (Pirfenidone), a treatment for pulmonary fibrosis, which was the drug to be approved in the PRC as a Class 1.1 new drug. Additionally, F351 (Hydronidone), a potential treatment for liver fibrosis, was designated by the CDE as a Breakthrough Therapy, underscoring our leadership in the research and development of innovative pharmaceuticals.

He was selected as one of the "Forbes China 100 most influential Chinese 2024".

GNI Group Overview

Global Expansion

A global biopharmaceutical company (TSE: 2160) that leverages the Chinese and U.S. markets to achieve sustainable business growth from its headquarters in Japan

Business Composition

① Pharma ② Biotech ③ Medtech

Priority disease areas: fibrosis, pain, cancer, orthopedics

Global Network

Major geographical operations : Japan, PRC, U.S., Australia

Subsidiaries and affiliates：26

Number of employees ：990 (as of December 2025)

R&D and Sales

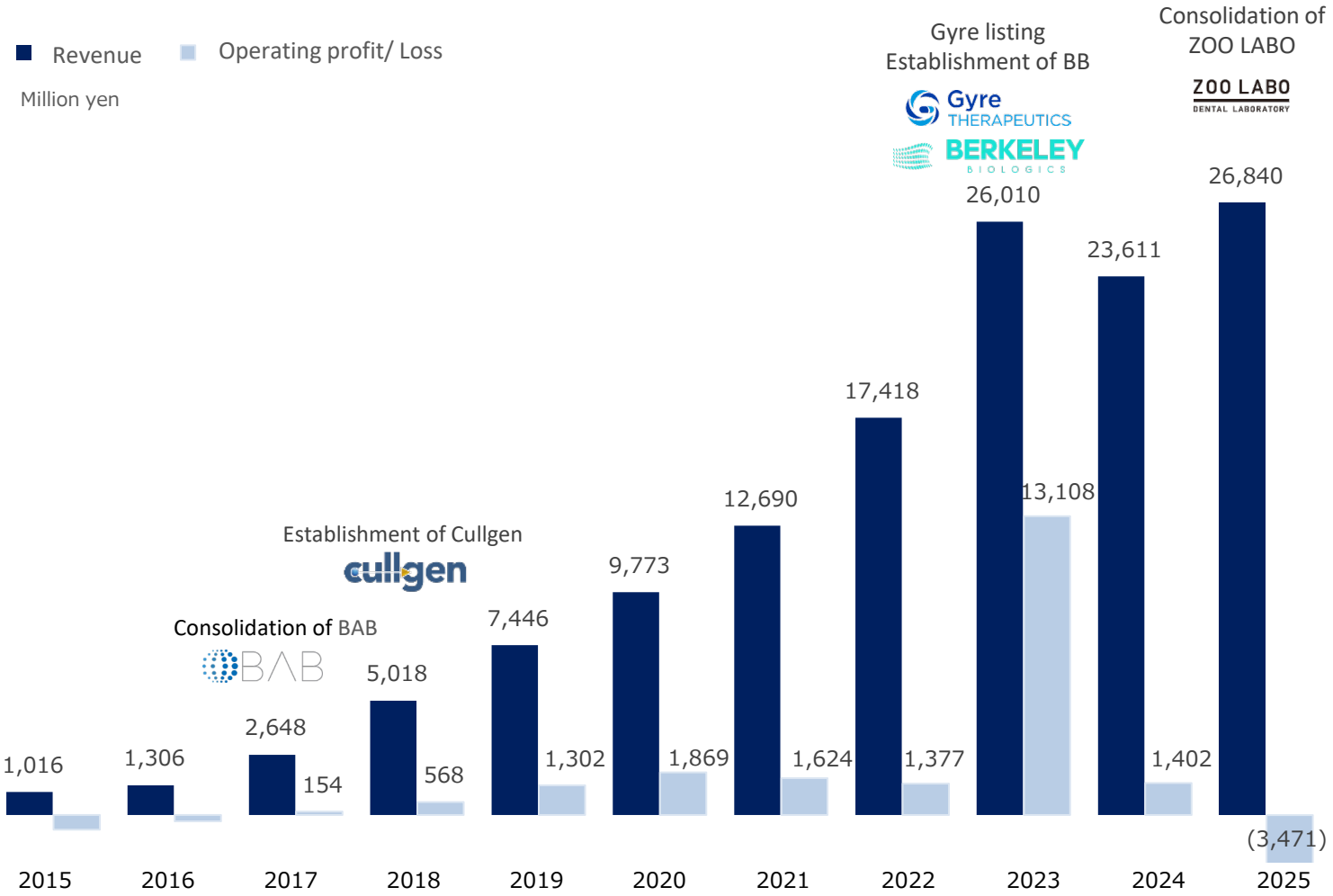
Structured R&D pipeline and marketed products：23 (as of December 2025)

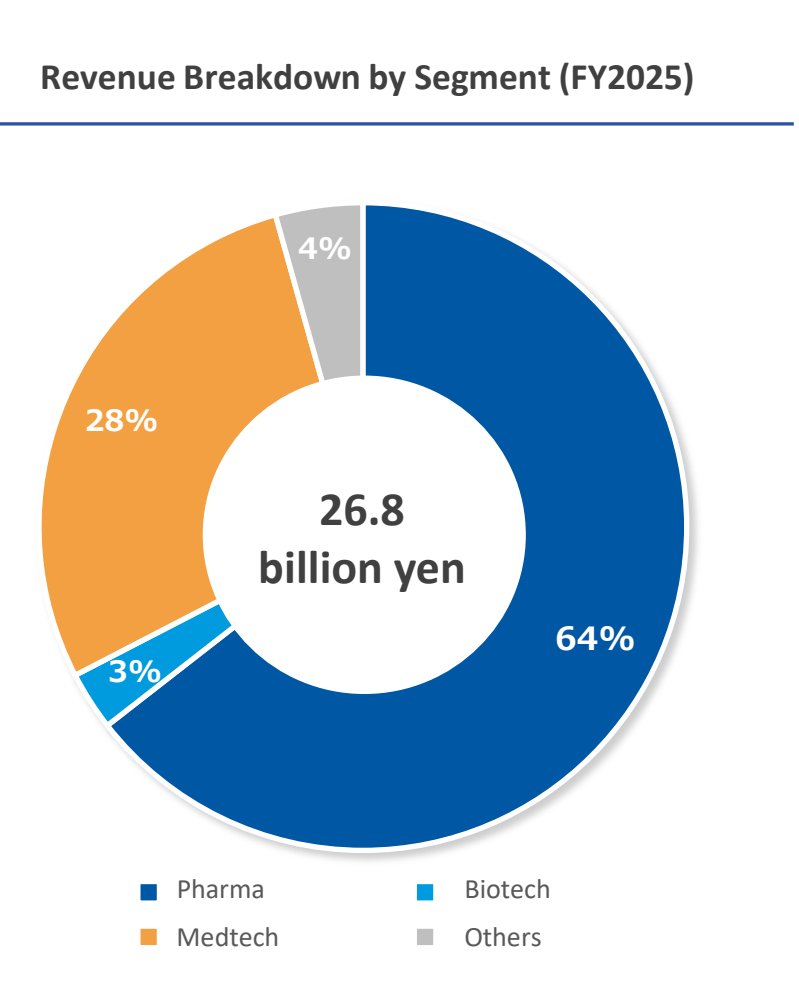
Hospitals and pharmacies in PRC：3,000

Comprehensive sales ：400

Link to Historical Performance

Aiming to become a Global BioPharma company, building a foundation in the pharma, Biotech, and medtech



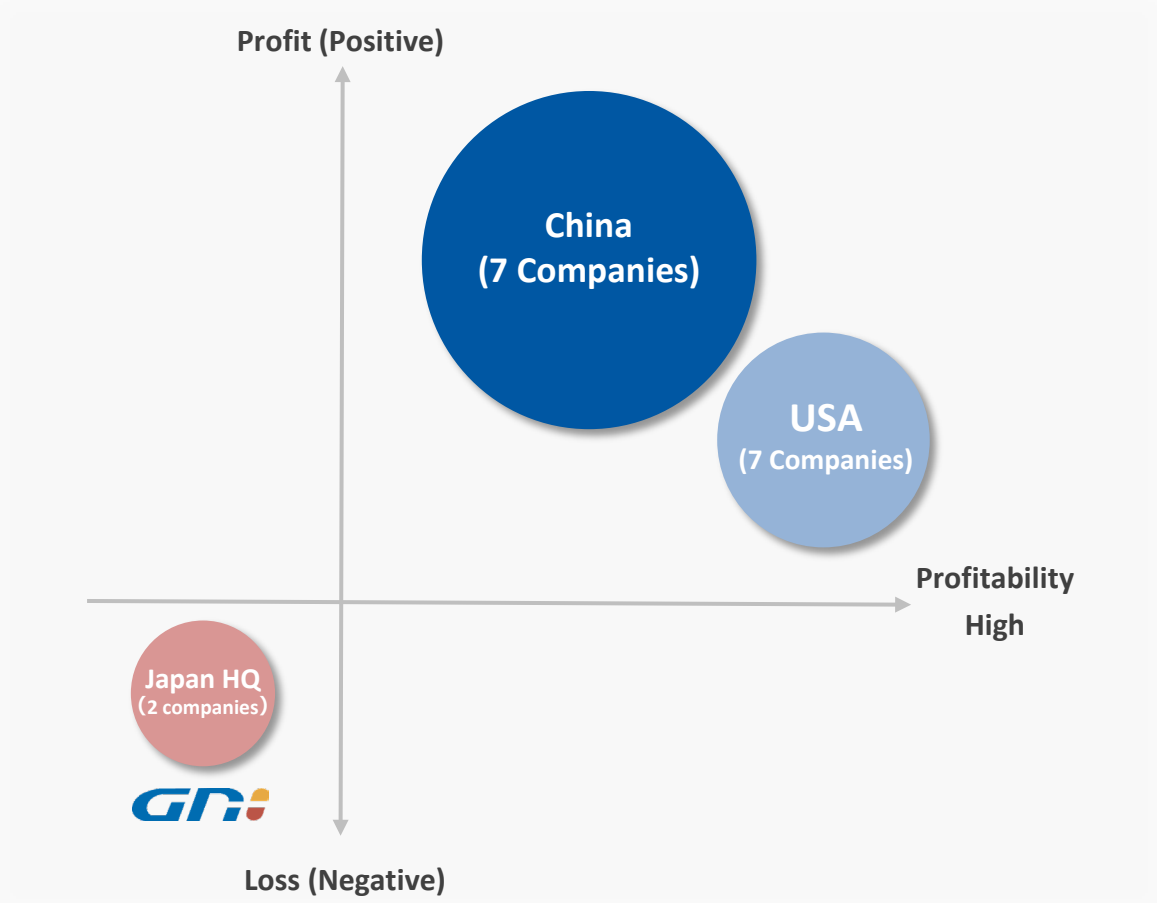


Strategic Significance of the Acquisition: Building a Profitable Foundation for the Japan Business

Aiming to Become a Global BioPharma, with Japan Business Profitability as the Next Growth Driver

[Current Situation] Profit by Region

The Japan headquarters continues to record losses due to the absence of revenue-generating businesses.



Resolve Structural Losses at the Japan Headquarters and Establish a Profitable Foundation

By securing stable revenue sources, the Company aims to cover headquarters-related expenses and transition to a profit-generating structure, targeting profitability in the Japan business.

Achieve Standalone Profitability and Cash Flow Generation at the Headquarters

Transition to a structure where the Japan business generates stable profits and cash flow, thereby enhancing financial soundness and investment capacity.

Reduce Dependence on Overseas Subsidiaries and Stabilize the Portfolio

Shift from a profit structure centered on the U.S. and China to a more diversified structure by improving profitability in the Japan business, building resilience against external environmental changes.

Note: Number of companies is calculated based on consolidated subsidiaries.

Establishing a Sustainable Growth Platform Across the U.S. and China

cullgen

Next-generation drug discovery engine

A drug discovery platform company in the U.S. and China based on the uSMITE™ technology platform.

Gyre PHARMACEUTICALS

Clinical development, manufacturing, and commercialization in China

Leveraging China's cost competitiveness and development infrastructure, Gyre conducts clinical development, manufacturing, and commercialization, achieving global-quality standards at lower cost.

Gyre THERAPEUTICS

Integrated pharmaceutical company across the U.S. and China

An operating company overseeing pharmaceutical businesses in both the U.S. and China.

Post-Combination Gyre Therapeutics: At-A-Glance

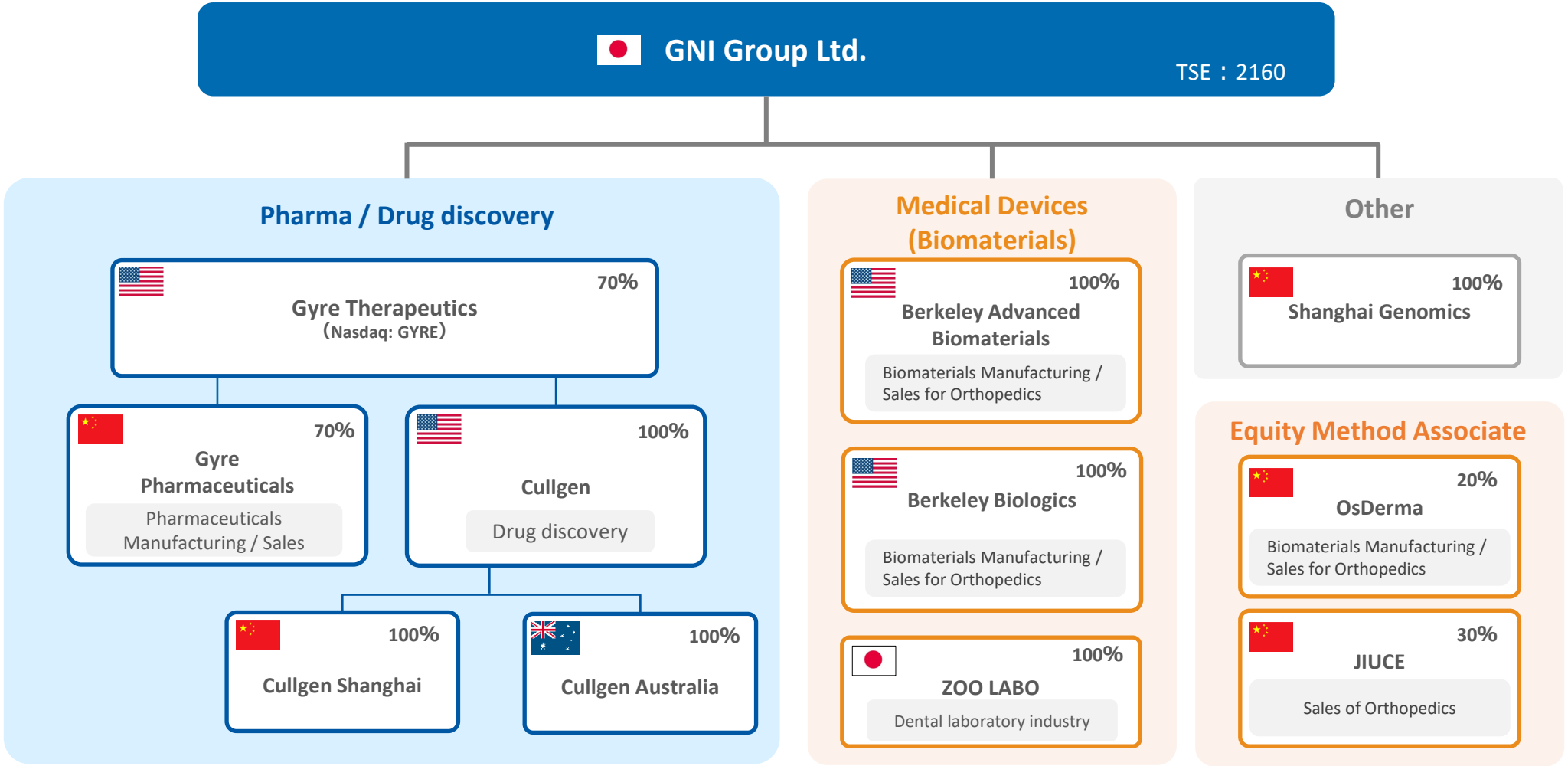
Gyre Therapeutics completed the transaction to make Cullgen a wholly owned subsidiary on May 4, 2026

Company Name	Gyre Therapeutics, Inc. (Nasdaq: GYRE)
Company Headquarters	San Diego, CA, with subsidiaries in Beijing and Shanghai
Post-Merger Leadership	• Ying Luo – President & CEO • Yue Xiong – CSO • Ping Zhang – Chairman • Thomas Eastling – CFO
Therapeutic Assets	**10 announced therapeutic programs:** **1** Marketed **1** NDA **2** Phase 2 **3** Phase 1 **3** IND-enabling studies + line extensions
Therapeutic Areas Addressed	• Inflammation / Pain • Cancer
WW Employees	**~740 Total:** ~170 R&D ~85 Manufacturing ~370 Sales & Marketing ~115 G&A

Strengths and Growth Strategies Following the Merger

1. Robust and balanced therapeutic pipeline including assets from discovery to development, with established manufacturing and commercialization operations
2. Utilization of highly efficient and cost-effective drug discovery capabilities in China to advance risk-mitigated products to the United States
3. Strong foundation in protein degrader development provides distinct advantage for the development of DACs as next generation ADC therapeutics
4. Accomplished management team in the United States with extensive international business operations experience

Main Group Structure



*This group structure chart has been reorganized for the purpose of improving readability. Some group companies are not shown in the chart; however, this does not imply that such companies have been dissolved or sold. Ownership ratios are rounded and may differ from the actual.

Robust Portfolio: Addressing Inflammatory Diseases, Pain and Cancer

IND Enabling	Phase 1	Phase 2	Phase 3	NDA Filed	Marketed
CG620953 TYK2/JAK1 Degrader for Inflammatory Diseases	**F351 (hydronidone)** MASH-Associated Liver Fibrosis + CHB	**CG001419** Acute and Chronic Pain (IND filed)	**ETUARY™ (pirfenidone)** Pneumoconiosis Line Extension	**F351 (hydronidone)** CHB-associated Liver Fibrosis	**ETUARY™ (pirfenidone)** Idiopathic Pulmonary Fibrosis (IPF)
CG923308 CDK2/Cyclin E Degrader for Solid Cancers		**F573** Acute Liver Failure (ALF)	**ETUARY™ (pirfenidone)** Radiation Induced Lung Injury Line Extension		
F528 Chronic Obstructive Pulmonary Disease (COPD)					

Degrader

The table above presents the major development pipeline and does not represent the entirety of the Group's pipeline.
The pipeline is subject to change by Gyre Therapeutics and Cullgen.

2. Q1 FY2026 Segment Results

Pharma

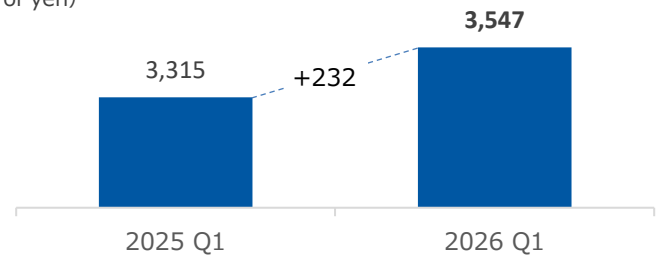
Financial Results

Millions of yen	FY2021 Actual	FY2022 Actual	FY2023 Actual	FY2024 Actual	FY2025 Actual	FY2025 (Quarterly) Q1	FY2026 (Quarterly) Q1	Inc. / (Dec)	FY2026 Forecast
Revenue	9,868	13,346	15,742	15,847	17,314	3,315	**3,547**	**232**	16,000
Operating profit	2,501	3,735	4,054	4,003	3,213	810	**(40)**	**(850)**	–
Operating profit margin	*25.3%*	*28.0%*	*25.8%*	*25.3%*	*18.6%*	*24.4%*	***(1.2)%***		

Financial Summary: Revenue increased year on year, supported by steady performance of existing products

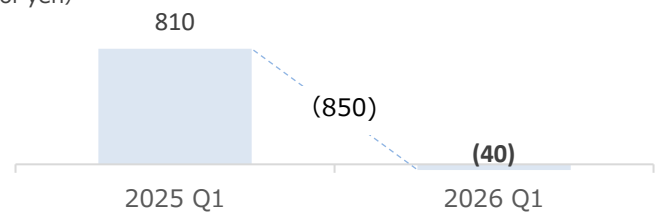
Revenue

(Millions of yen)



Profit/ Loss

(Millions of yen)



Factors Behind Changes in Operating Profit/Loss (YoY)

Operating loss reflected upfront growth investments, mainly F351 launch preparation and non-cash expenses for Gyre's previously issued stock options.

- **Marketing expenses, including preparation for F351 commercialization: +JPY 539 million**
  Expenses were recorded for initial preparation activities for the launch of F351, including awareness-building activities*.
  Investments were also made in market promotion activities for Contiva™ and Etorel™, which were launched in the previous year.

- **Stock-based compensation expenses: +JPY 415 million**
  Expenses were recorded due to the remaining accounting treatment related to performance-linked stock options granted in the previous year, which are tied to the progress of the F351 project.
  These Gyre stock options were granted to Gyre Pharmaceuticals' R&D personnel.
  The majority of these expenses have already been recorded in Q1 based on the current-year budget.

*based on GNI's own view

Process Toward F351 Launch

Received formal acceptance notification for the New Drug Application (NDA) on May 13, 2026. Currently under review with Priority Review designation.

	Description	Progress
1. Pre-NDA Meeting	Prior consultation with the regulatory authority before NDA submission	Completed
2. Priority Review Designation	Designated under a review system intended to promote the development of new drugs with high clinical value and to expedite regulatory review.	Designated (Announced on March 18, 2026)
3. NDA Submission	Submitted the New Drug Application for F351 in China	Completed (Announced on March 24, 2026)
4. Formal Review	Confirmation of formal requirements and completeness of the submitted documents	Completed
5. Issuance of Acceptance Number	NDA formally accepted following formal review by the CDE	Issued (Announced on May 13, 2026)
6. Technical Review / Substantive Review ●	**Scientific and expert review of efficacy and safety based on submitted data; the most important review stage. Reviewed under an accelerated timeline compared with the standard review period under the Priority Review system.**	**Ongoing**
7. NDA Approval/ Completion of GMP Compliance Confirmation	NDA approval is granted following the technical review and confirmation of GMP compliance, including the manufacturing and quality control systems at the manufacturing site.	Upcoming
8. Launch / Start of Sales	Launch after obtaining approval, drug price determination, and establishment of sales and supply systems	Upcoming
9. Application for Reimbursement Listing and Drug Price Negotiation	Application and price negotiation for inclusion in China's National Reimbursement Drug List	Upcoming

*Includes GNI Group's own interpretation.

ETUARY™ Indication Expansion Strategy: Expansion into Cancer Treatment-Related Pulmonary Complications with Limited Existing Therapies

Pirfenidone (ETUARY™) completed enrollment of the first patient in a Phase 2/3 trial for radiation-induced lung injury (RILI) as part of its indication expansion strategy (April,2026)

Disease Overview

Radiation-induced lung injury (RILI) is a pulmonary injury that may occur after radiotherapy for thoracic tumors. It is a cancer treatment-related complication that can cause symptoms such as cough, shortness of breath, and reduced lung function. Given the limited treatment options and the potential progression to pulmonary fibrosis, RILI represents an area of high unmet medical need.

Market Size

- The number of RILI patients in China is expected to increase to 120,000 by 2032. The market size is expected to expand to USD 490 million, or approximately JPY 77.0 billion, at a CAGR of 4.43%.
- As a related area that may be associated with RILI, checkpoint inhibitor pneumonitis (CIP) is expected to reach approximately 345,000 patients and a therapeutic drug market size of approximately USD 680 million, or approximately JPY 110.0 billion, by 2032.

Source: Frost & Sullivan and publicly available materials from Gyre Therapeutics, Inc.

In a Phase 2 trial led by Sun Yat-sen University Cancer Center in China, pirfenidone was reported to improve DLCO%*1, an indicator of pulmonary diffusion capacity, in RILI patients and suggest its therapeutic potential.*2

Positioning of the trial：	This was a Phase 2 trial led by external medical institutions, including Sun Yat-sen University Cancer Center in China. Gyre Pharmaceuticals provided pirfenidone as the study drug. The trial is positioned as external clinical evidence suggesting the therapeutic potential of pirfenidone for RILI.
Trial overview：	A multicenter, randomized trial using pirfenidone in Grade 2/3 RILI patients. n=134.
Key results:	At 24 weeks, DLCO%, an indicator of pulmonary diffusion capacity, worsened by 2.4% in the control group treated with steroids alone, while it improved by 8.0% in the pirfenidone combination group. The difference was significant, p=0.0010. The incidence of serious adverse events in this study was not materially different between the two groups, and there were no treatment-related deaths.

Phase 2/3 Adaptive Design

Based on interim analysis results, the Group aims to improve development efficiency and shorten the development period by optimizing the sample size and dosing design.

*1 DLCO% is a pulmonary function indicator that reflects the lungs' ability to transfer oxygen from the lungs into the bloodstream. In RILI, DLCO% may decline due to lung inflammation and fibrosis, and it is one of the indicators used to assess the severity of lung injury and treatment effects.

*2 This trial is an externally led trial conducted by medical institutions and is different from the Phase 2/3 trial currently being conducted by the Group.

Source:Hou Z, Dong B, Yao Q, et al. "Pirfenidone for grade 2 and grade 3 radiation-induced lung injury: a multicentre, open-label, randomised, phase 2 trial." The Lancet Oncology, Vol. 26, Issue 12, pp. 1552–1562, 2025. doi:10.1016/S1470-2045(25)00515-7.

Major Pharmaceutical & Drug Discovery (Candidate)

Pharmaceutical products

ETUARY™

(Generic name：Pirfenidone) Chinese：艾思瑞®

- Treatment for idiopathic pulmonary fibrosis (IPF)
- The Group's flagship product

Contiva™

(Generic Name: Avatrombopag Maleate Hydrochloride) Chinese: 康曲欣®

- Launched in March 2025
- A liver disease–related therapeutic, establishing sales channels in preparation for F351's launch(for thrombocytopenia caused by chronic liver disease and chronic idiopathic thrombocytopenia)

Etorel™

(Generic Name: Nintedanib Esylate) Chinese Name: 伊妥瑞®

- Launched in June 2025
- Indicated for SSc-ILD and PF-ILD

Drug Discovery

F351

（Generic name：Hydronidone）

- A potential blockbuster drug candidate for liver fibrosis, for which no treatments currently exist[#]（May 23, 2025: Positive topline data from the Phase 3 clinical trial announced）
- Recognized as a 'Breakthrough Therapy' by the China National Medical Products Administration in 2021

F528

- A next-generation potential blockbuster drug candidate for chronic obstructive pulmonary disease (COPD)[*]
- COPD is the fourth leading cause of death worldwide, causing 3.5 million deaths in 2021, equivalent to approximately 5% of all deaths globally.
- An estimated 100 million patients in the PRC, yet no curative treatments currently exist (For details on F528, Q2 FY2025 financial results presentation, pp. 40–44.)
- IND submission planned for the first quarter of 2027.

[*] based on GNI's own view

Biotech

Financial Results

Millions of yen	FY2021 Actual	FY2022 Actual	FY2023 Actual	FY2024 Actual	FY2025 Actual	FY2025 (Quarterly) Q1	FY2026 (Quarterly) Q1	Inc. / (Dec)	FY2026 Forecast
Revenue	0	0	5,805	1,439	789	353	**172**	**(181)**	**544**
Operating profit	(1,920)	(2,794)	2,374	(3,371)	(3,958)	(1,138)	**(1,048)**	**90**	**–**

Financial Summary: Completion of Cullgen's Wholly Owned Subsidiarization by Gyre Therapeutics

- R&D expenses remained at the same level as the previous year: JPY 608 million
- Expenses related to Cullgen's standalone listing decreased
- Gyre Therapeutics recorded approximately JPY 400 million in advisory fees related to the acquisition of Cullgen(included in the Other segment)

Key Business Impact of the Gyre-Cullgen Subsidiary Reorganization

Leveraging Gyre's listed-company platform to enhance capital market access, while reviewing post-integration development strategies, timelines, and resource allocation*1

1.	Gain on waiver of accrued interest payable	Expected to be recorded as a one-time gain in Q2	The amount is currently under discussion with the auditor
2.	Elimination of accrued interest payable recorded on a recurring basis	Future expense burden to be eliminated	No additional accrued interest payable is expected to arise after the completion of the wholly owned subsidiarization. Reference: accrued interest payable of approximately JPY 1.5 billion was recorded in FY2025
3.	Change in the Group's attributable share of Cullgen's profit/loss	Impact on profit attributable to owners of the Company will change	Previously, the Company held approximately 40% of Cullgen. After the reorganization, the Company indirectly holds Cullgen through Gyre, in which the Company holds approximately 70%

*1 Includes GNI Group's own interpretation.

*2 Ownership ratios are calculated based on the issued and outstanding shares of Gyre Therapeutics and Cullgen as of the announcement date of this transaction and may change due to the exercise of stock options or other factors. The Company's ownership includes interests held through its wholly owned subsidiaries.

Major Drug Discovery of Cullgen (Candidate)

Aiming to create new drugs by leveraging its proprietary TPD platform, uSMITE™

Drug Discovery

CG001419 (Acute and chronic pain)

- **Potential to become a first-in-class oral pan-TRK protein degrader for pain treatment**
- Only one non-NSAID, non-opioid analgesic has been approved in the past 25 years (for acute pain)[1]
- The global acute and chronic pain market is estimated to be in the tens of trillions of yen
- Phase 1 in Australia was completed in December 2025. No serious adverse events were observed and the results were favorable
- Phase 2 in the U.S. for acute pain following bunionectomy is scheduled to start in the 1H of 2026

CG001419 (Solid Tumors)

- Preclinical studies demonstrate strong efficacy against solid tumors with various oncogenic TRK abnormalities, including NTRK gene fusions and overexpression of wild-type TRK proteins
- Phase 1 is ongoing in the PRC, with patient enrollment for the dose-expansion part expected to begin in Q1 2026
- In the first 18 subjects, no DLTs (dose-limiting toxicities), drug-related SAEs, or Grade ≥3 drug-related adverse events have been observed

CG009301 (Leukemia, MYC)

- GSPT1 is a factor that regulates protein translation termination and plays an important role in leukemia stem cells and tumor cells with MYC overexpression
- While GSPT1 has been considered a challenging target for drug discovery, Cullgen has developed CG009301, a degrader that selectively and potently degrades GSPT1
- Preclinical studies have confirmed selectivity, efficacy, and safety
- Phase 1 began in the PRC in April 2025, and the dose-escalation phase is currently ongoing

CG620953 (Inflammatory Diseases)

- Selective targeting of TYK2 for autoimmune diseases; selective TYK2 degraders have demonstrated efficacy in preclinical models of systemic lupus erythematosus and rheumatoid arthritis
- Large market opportunity:
  - Global SLE patient population: ~12.5 million[2]
  - Rheumatoid arthritis patients: ~18 million[3]
  - U.S. SLE patients (2018): ~204,000[4]
- IND for the Phase 1 is planned to be filed in the PRC in Q1 2027

CG923308 (Breast cancer and multiple solid tumors)

- IND for the Phase 1 is planned to be filed in the U.S. and the PRC in Q1 2027

1. https://www.precedenceresearch.com/pain-management-drugs-market
2. https://www.psoriasis.org/psoriasis-statistics/
3. https://www.who.int/news-room/fact-sheets/detail/rheumatoid-arthritis
4. https://www.niams.nih.gov/health-topics/lupus/basics/symptoms-causes

In-house Pipeline (based on GNI's own view)

Product	Modality| Target	Indication	Location	Development Progress
F528	Small molecule	Chronic Obstructive Pulmonary Disease (COPD)	Global	Plan to submit an IND in Q1 2027
F351 (Hydronidone)	Small molecule	MASH-Associated Liver Fibrosis	Global	Plan to submit an IND application in 2026
	Small molecule	CHB-Associated Liver Fibrosis	PRC	NDA accepted in May 2026
ETUARY™ (Pirfenidone)	Small molecule	Idiopathic Pulmonary Fibrosis (IPF)	PRC	
	Small molecule	Pneumoconiosis	PRC	Phase 3 expected to be completed in Q3 2026
	Small molecule	Radiation-Induced Lung Injury With or Without Immune-Related Pneumonitis	PRC	First patient enrolled in Phase 2/3 trial in Q1 2026
	Small molecule	Dermatomyositis Interstitial Lung Disease (DM-ILD)	PRC	
	Small molecule	Systemic Sclerosis-associated Interstitial Lung Disease (SSc-ILD)	PRC	
	Small molecule	Diabetic Kidney Disease (DKD)	PRC	
F573	Small molecule	Acute Liver Failure (ALF)/ Acute-On-Chronic Liver Failure (ACLF)	PRC	
F230	Small molecule	Pulmonary Arterial Hypertension (PAH)	PRC	Phase 1 trial completed in Q4 2026
TPD/ DAC				
CG001419	Degrader | TRK	Acute and Chronic Pain	Global	Planned to initiate a Phase 2 in Q2 2026 (U.S.)
CG001419	Degrader | TRK	Solid Tumors	Global	Phase 1 completion expected in Q4 2027 (PRC)
CG009301	Degrader | GSPT1	Leukemia and MYC+ cancers	Global	Phase 1 completion expected in 2H of 2027 (PRC)
CG923308	Degrader | CDK2	Breast cancer and multiple solid tumors	Global	IND filing expected in Q1 2027 (U.S. and PRC)
CG620953	Degrader | TYK2/ JAK1	Inflammatory Diseases	Global	IND filing expected in Q1 2027 (PRC)
Undisclosed	DAC | Epigenetic Factor	Prostate, lung & bladder cancers	Global	
Undisclosed	DAC | Translation Factor	Blood cancers &multiple solid tumors	Global	
Undisclosed	Degrader | cAMP Regulator	Fibrotic diseases	Global	

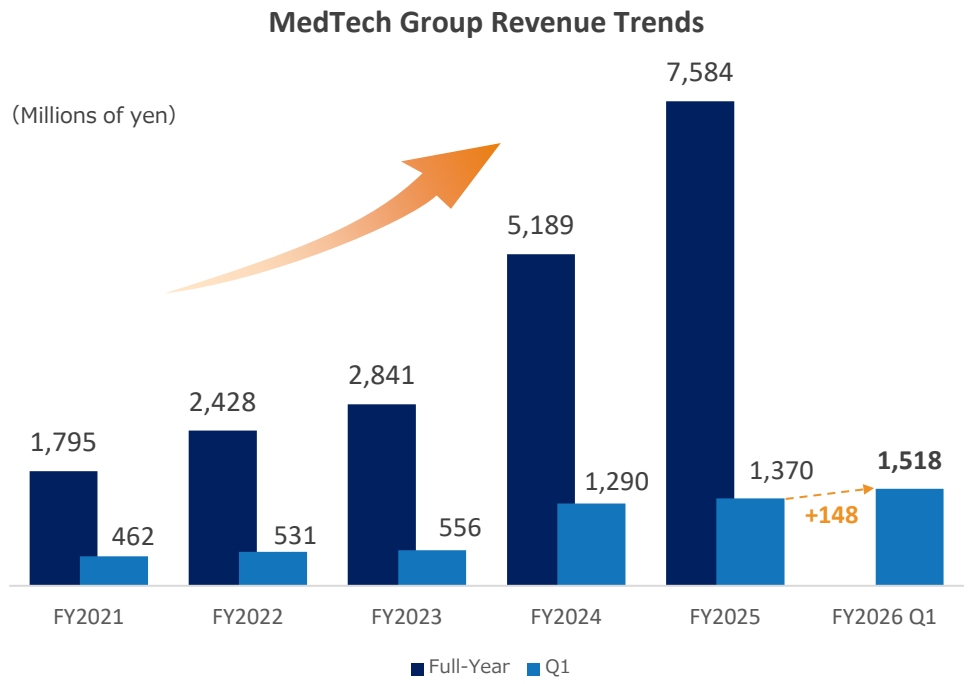
Note: Development details and timelines may be subject to change depending on progress.

Medtech

Financial Results

Millions of yen	FY2021 Actual	FY2022 Actual	FY2023 Actual	FY2024 Actual	FY2025 Actual	FY2025 (Quarterly) Q1	FY2026 (Quarterly) Q1	Inc. / (Dec)	FY2026 Forecast
Revenue	1,795	2,428	2,841	5,189	7,584	1,370	**1,518**	**148**	**9,674**
Operating profit	844	1,110	1,133	942	1,274	245	**(246)**	**(491)**	**–**

Financial Summary: M&A-Driven Business Expansion Contributed to Record-High First-Quarter Revenue.



Revenue

- ZOO LABO, which became a subsidiary in the previous year, contributed to revenue in the dental laboratory business.
- In the U.S. biomaterials business, BAB remained solid, mainly driven by sales to existing customers, and revenue increased by 22% year on year.
- BB was affected by order postponements from a major customer due to U.S. Medicare system revisions, which became apparent in the current period. The Company plans to restore its revenue base through the expansion of its new business, skin graft products, outside the U.S.

Profit/ Loss

- Profit declined year on year, reflecting the impact of U.S. Medicare system changes on BB (Source: Q3 2025 earnings presentation); however, ZOO LABO and BAB remained profitable.
- Upfront investment expenses continued, including BAB's private-label product sales initiatives and regulatory applications related to BB's skin graft business.

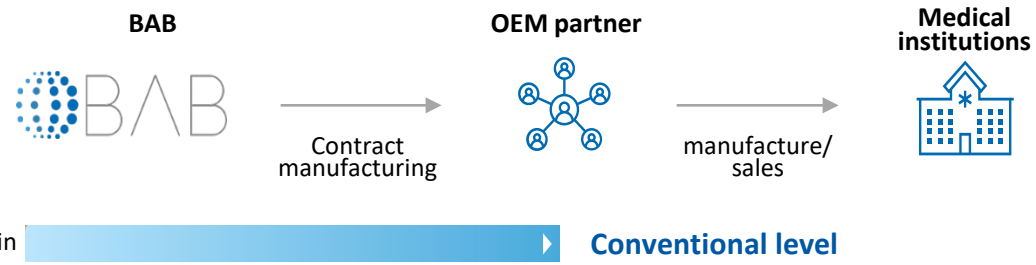
The Medtech Group's First Proprietary Brand Strategic Product

Sales of private-brand (PB) products based on the Group's aim to establish an in-house manufacturing and sales framework

- The strategic products that BAB plans to sell are highly biocompatible and effective for various types of damage, including surgical injuries and burns.
- BAB has submitted Marketing application to the U.S. FDA in March 2026; launch expected within FY2026, subject to approval.

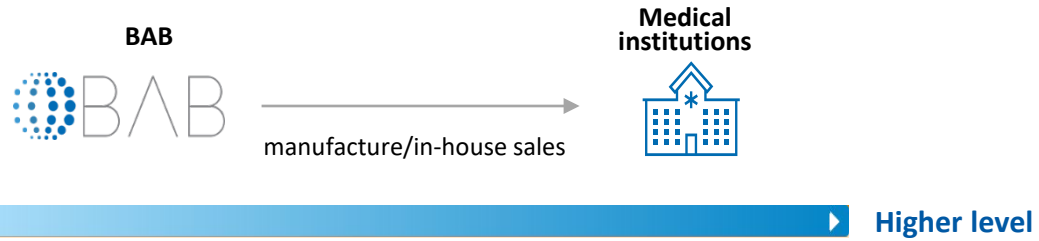
[Conventional] OEM Model

Existing contract manufacturing model before in-house integration



[Proprietary Brand Strategic Product] Vertically Integrated Model

High-profitability model through integration of the value chain



Significant Profitability Improvement

Eliminating intermediary margins and capturing value across the entire value chain enables higher profitability.

Establishment of Sustainable Competitive Advantage

By developing a proprietary brand, the Company aims to secure unique product value and pricing competitiveness independent of OEM contracts.

[Medtech] Expansion into OsDerma and Medical Aesthetics Market

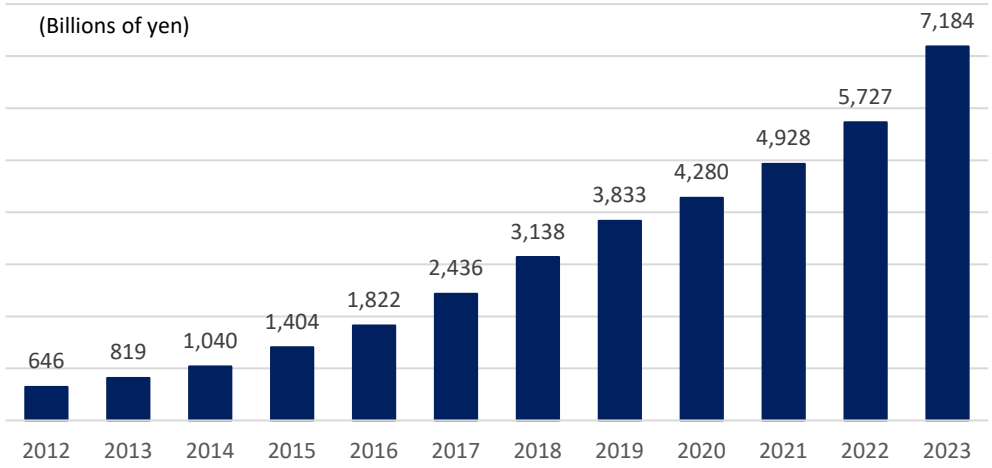
GNI Group's Business Platform Synergies to be Realized

Expand market share in the high-end cosmetic medicine market and establish a brand

OsDerma's DermiraCa®

- Highly biocompatible and biodegradable product containing hydroxyapatite (HAp), a major component of bones and teeth
- Promotes tissue repair and collagen regeneration, with proven safety and efficacy in clinical trials
- Both immediate and sustained regenerative effects

Medical Aesthetics Market Size in the PRC 2012-2023*



Competitive advantage over peers

Tighter regulations on off-label use in the cosmetic surgery field is a tailwind for the company.

1. **Synergies with Medtech Group**
   - Proof of competitive functional materials
   - Integrated production from raw materials to manufacturing, including in-house development of manufacturing facilities, enables high profit margins

2. **Synergies with Drug Discovery Group business**
   - While other companies in the industry have limited experience in clinical trials, we have extensive experience
   - Authoritative investigators and hospitals Established network

3. **Capital strength of the group**
   - Other companies need to raise funds for clinical trials

State of Progress

May 2026

A multicenter, investigator-initiated clinical trial led by Professor Luo Chengji, a renowned plastic surgery specialist in China, and conducted jointly with six authoritative medical institutions, including Beijing Union Hospital, has enrolled 163 subjects. As of now, 50% of the subjects have completed the six-month observation period. The trial is expected to be completed around November 2026. If efficacy and safety are confirmed, an application for marketing approval will be submitted to the NMPA.

Note: OsDerma Medical, Inc. is accounted for under the equity method, with our company holding a 20% ownership interest.
*Source: iResearch (converted to JPY by GNI Group)

Other Segment

The Other segment consists of 14 companies, including GNI Group (the Company), which holds global headquarters functions, and Gyre Therapeutics, a Nasdaq-listed company that conducts research and development in the United States, as well as other entities making strategic investments to support future growth.

Financial Results

Millions of yen	Q1 2025	Q1 2026	Inc. / (Dec.)	Factors for increase/decrease
Revenue	**279**	**281**	**2**	
Operating profit/ Loss	**(898)**	**(1,423)**	**(525)**	
GNI Group	(805)	(351)	454	• Corporate fixed costs: JPY 157 million • Share valuation loss: JPY 195 million (Reference: disclosed on December 22, 2025)
Gyre Therapeutics	(235)	(991)	(756)	• Advisory fees related to Cullgen's wholly owned subsidiarization: JPY 400 million • Development expenses for the U.S. IND submission of F351: JPY 160 million
Other 12 companies	143	(80)	(224)	

Note: Calculated based on IFRS.

3. Q1 FY2026 Financial Highlights

Q1 FY2026 Financial Highlights

Strategic investments advanced for the next growth phase, driven by F351 launch preparations, Gyre-Cullgen integration, and U.S. R&D progress

- Revenue increased year-on-year, supported by the steady performance of the pharmaceutical business and growth in the MedTech business.
- Operating loss reflected upfront expenses related to F351 launch preparations, Gyre stock-based compensation, and costs associated with the full consolidation of Cullgen.
- Following the formal acceptance of the NDA, F351 has moved into an important stage toward approval and launch.
- Through the integration of Gyre and Cullgen, the Group has established a growth platform across the U.S. and China that integrates commercialization, clinical development, and drug discovery.
- Despite temporary external headwinds, the MedTech business recorded its highest-ever Q1 revenue.

Consolidated Income Statement

Revenue increased by JPY 206 million year on year, mainly due to the contribution from M&A conducted in Q4 2025.

Millions of yen	2025 Q1	2026 Q1	Inc. / (Dec.)	Factors for increase/decrease
Revenue	**5,320**	**5,526**	**206**	• Solid pharmaceutical performance and contribution from ZOO LABO consolidation
Gross profit	**4,116**	**4,025**	**(91)**	
SG&A	3,827	5,459	1,632	• Increase mainly due to share-based compensation expenses, pharmaceutical product promotion and F351 launch preparation costs, and Cullgen acquisition-related expenses of JPY 400 million
R&D	806	1,053	246	• Increased R&D expenses for Gyre's U.S. F351 IND preparation
Operating profit	**(772)**	**(2,749)**	**(1,977)**	
Income before income taxes	(837)	(3,187)	(2,350)	
Net profit	**(1,266)**	**(3,376)**	**(2,110)**	
Profit attributable to owners of the parent	**(530)**	**(2,127)**	**(1,597)**	

Segment

Millions of yen	Pharma		Biotech		Medtech		Others	
	2025 Q1	**2026 Q1**	2025 Q1	**2026 Q1**	2025 Q1	**2026 Q1**	2025 Q1	**2026 Q1**
Revenue	3,315	**3,547**	353	**172**	1,370	**1,518**	279	**281**
Operating profit	810	**(40)**	(1,138)	**(1,048)**	245	**(246)**	(898)	**(1,423)**

Note: The performance of Gyre Therapeutics, Inc. is included in "Others."
The difference between the sum of each segment and the consolidated financial statements is due to consolidation adjustments.

Consolidated Balance Sheet

Based on the use of proceeds from the public offering conducted in the previous fiscal year, the Company provided a loan of JPY 1,214 million to BB to support the growth of the Medtech business (Eliminated in consolidation as an intercompany transaction).

Millions of yen	FY2024 Q4	FY2025 Q4	FY2026 Q1	Inc. / (Dec.)	
Total non-current Assets	**42,720**	**43,057**	**45,245**	**2,188**	
Goodwill	15,994	16,648	16,980	333	• Increase entirely due to foreign currency translation
Intangible assets	11,026	12,347	13,263	916	• F351 NDA application expenses and progress in Phase 3c development by Gyre Pharmaceuticals
Total Current Assets	**29,222**	**40,734**	**37,350**	**(3,383)**	
Trade accounts receivable	6,236	8,056	6,219	(1,837)	• Progress in collection of trade receivables related to Gyre Pharmaceuticals' record-high sales in the previous quarter
Inventories	2,529	3,752	4,119	367	
Cash and cash equivalents	10,115	21,101	19,869	(1,232)	
Total Liabilities	**32,229**	**31,948**	**32,076**	**128**	
Total non-current Liabilities	19,764	22,354	22,917	563	• Increase in accrued interest on Cullgen's preferred shares, accounted for as financial liabilities until May 4, the completion date of Gyre's acquisition of Cullgen
Total current Liabilities	12,464	9,594	9,159	(435)	
Total Equity	**39,713**	**51,842**	**50,519**	**(1,323)**	
Capital and Other Components of Equity	19,887	35,434	35,562	128	
Retained earnings	9,888	5,644	3,516	(2,128)	
Other Components of Equity	6,669	9,240	10,950	1,710	
Equity attributable to owners of the parent company to total assets	36,446	50,320	50,030	(290)	
Non-controlling Interests	3,267	1,522	489	(1,033)	

Consolidated Balance Sheet / Goodwill and Intangible Assets

Goodwill and intangible assets increased by JPY 1,249 million quarter on quarter. The increase was mainly driven by higher capitalized development costs related to F351, while the remaining increase was primarily attributable to foreign currency translation effects.

Breakdown			JPY Amounts（millions of yen）				Foreign Currency（Local Currency Basis）			
			FY2024 Q4	FY2025 Q4	FY2026 Q1	Inc. / (Dec.)	FY2024 Q4	FY2025 Q4	FY2026 Q1	Unit
Goodwill			**15,994**	**16,648**	**16,980**	**333**				
	Gyre Pharmaceuticals		188	194	200	6	8.7	8.7	8.7	Million RMB
	Gyre Therapeutics		7,616	7,535	7,694	159	48.1	48.1	48.1	Million USD
	Berkeley Advanced Biomaterials		6,653	6,584	6,724	140	42.1	42.1	42.1	Million USD
	Berkeley Biologics		1,230	1,217	1,243	26	7.8	7.8	7.8	Million USD
	ZOO LABO		–	1,081	1,081	0	–	1,081	1,081	Million JPY
	GNI Hong Kong		35	34	35	1	0.2	0.2	0.2	Million USD
Intangible assets			**11,026**	**12,347**	**13,263**	**916**				
	Customer relationships	①	2,468	2,290	2,299	9	15.6	14.6	14.4	Million USD
	Brand（PPA）		69	63	63	0	0.4	0.4	0.4	Million USD
	Distribution rights	②	0	720	719	(1)	0	32.2	31.1	Million RMB
	Capitalized development costs		8,038	9,214	10,122	908				
		Gyre Therapeutics ③	4,745	4,696	4,796	100	30.0	30.0	30.0	Million USD
		Gyre Pharmaceuticals ④	3,293	4,517	5,325	808	152.0	202.0	230.5	Million RMB

① Customer relationships	Customer turnover over time at the acquired entity is recognized as amortization expense.
② Distribution rights	Gyre Pharmaceuticals holds the sales rights for Etorel™ (nintedanib), which was launched in June 2025.
③ Capitalized development costs (Gyre Therapeutics)	Includes the rights held by Gyre Therapeutics related to F351 (actual development expenses are not included).
④ Capitalized development costs (Gyre Pharmaceuticals)	R&D expenses for Phase 3 clinical trials conducted in China are capitalized as assets (including development expenses for Phase 3 and beyond of F351). After launch, amortization is scheduled over 10 years.

Cash Flow

Millions of yen	FY2025 Q1	FY2026 Q1	Note
Cash Flow from Operating Activities	(287)	(415)	• Although loss before income taxes of JPY 3,187 million had a significant impact, the cash flow deficit narrowed due to the collection of accounts receivable and stock-based compensation expenses of JPY 664 million, among other factors.
Cash Flow from Investment Activities	1,151	(916)	• Development-related expenditures for the F351 Phase 3c clinical trial were recorded as additions to intangible assets.
Cash Flow from Financial Activities	(619)	(139)	
Net effect of exchange rates changes	(427)	238	
Net (decrease)/ Increase in cash and cash equivalents	(183)	(1,232)	
Cash and cash equivalent at beginning of year	10,115	21,101	
Cash and cash equivalents at end of year	9,931	19,869	

R&D expense

- R&D expenses increased due to progress in development preparations for the U.S. expansion of F351 at Gyre.
- The increase in capitalized development expenses was mainly attributable to JPY 808 million recorded by Gyre Pharmaceuticals, reflecting NDA-related expenses for the commercialization of F351 and progress in the Phase 3c trial.
- The capitalization of F351 Phase 3 clinical trial expenses is based on accounting standards in China.

Millions of yen	FY2022 Actual	FY2023 Actual	FY2024 Actual	FY2025 Q1	FY2026 Q1	Inc. / (Dec.)
Consolidated R&D expenses	2,557	2,811	3,298	806	**1,053**	246
Capitalized development costs	940	1,165	1,176	(173)	**908**	1,081
Total	3,497	3,976	4,474	633	**1,961**	1,327

FY2026 Consolidated Earnings Forecast

Consolidated Earnings Forecast: Revenue Forecast Remains Unchanged from the Previous Disclosure

Millions of yen	FY2024 Actual	FY2025 Actual	FY2026 Forecast
Consolidated Revenue	23,611	26,840	**27,158**
Pharma	15,847	17,314	**16,000***
Biotech	1,439	789	**544**
Medtech	5,189	7,584	**9,674**
Other	1,156	1,169	**940**

*based on GNI's own view
Gyre 8-K filed on May 7, 2026: Revenue guidance of $100.5–$111.0 million (¥15,600–¥17,200 million) remains unchanged.

Key Reasons for Non-Disclosure of Profit Forecasts

① R&D expenses in Biotech business	The scale and timing of clinical trials remain uncertain at this stage, as they depend on the progress and trends of future R&D activities, as well as decisions by regulatory authorities in each country, including the FDA.
② Uncertainty in upfront investments related to new drug approvals	As these investments largely depend on the timing of new drug approvals, the feasibility, timing, and scale of upfront investments in anticipation of future approvals remain uncertain at this stage.
③ Uncertainty in strategic investments in the MedTech business	Under the private-label brand strategy for future growth, multiple factors remain fluid at this stage, including the timing of obtaining U.S. FDA approvals, the feasibility of upfront investments, the scale of business expansion, such as global or regional expansion, and the use of in-house personnel or distributors.
④ One-time accounting factors associated with M&A (timing of recognition of debt extinguishment gains)	n connection with Gyre's acquisition of Cullgen, the Company expects to recognize a gain on waiver of obligations from external Group creditors. However, the actual amount to be recorded and other impacts on consolidated financial results, including advisory fees, are currently under discussion with the auditor.

FX: USD/JPY: 155.0　CNY/JPY: 21.0　　Note：Gyre Therapeutics,Inc. is included in the "Others" segment.

4. Supplementary Materials

**F351: Bring New Hope to Life,
Powering a Brighter Future for CHB Patients.**

Hepatitis is the second most common cause of death from infectious disease in the world

World Hepatitis Summit 9 April 2024

Estimated deaths from viral hepatitis will increase from 1.1 million to 1.3 million by 2022 (2019) 83% of which are hepatitis B

Second most common cause of death from infectious diseases in the world

Tied with tuberculosis as leading cause of death from infectious diseases 13% of those with chronic hepatitis B infection have been diagnosed (as of the end of 2022) About 3% are on CHB therapy

WHO: Global hepatitis report 2024 (p244)

- People infected with hepatitis B virus
  Global: 254 million
  China: 79.7 million

- Western Pacific Area (including China)
  Number of infected: 96.8 million
  Annual deaths: 518,000
  Chronic hepatitis B diagnosis rate: 25.5%
  Treatment rate after diagnosis: 23.2%
  Treatment rate for all hepatitis B infected: 5.9%

F351: Bring New Hope to Life, Powering a Brighter Future for CHB Patients.

An estimated 60-79.7 million people# in China are infected with hepatitis B virus

Stage	Description
1. HBV Infection	Infection with the hepatitis B virus. If the acute hepatitis does not resolve and becomes chronic, it is referred to as a persistent infection (HBV carrier). Infants are more prone to becoming carriers when infected.
2. Chronic Hepatitis B (CHB)	A condition in which the virus persists, causing ongoing inflammation in the liver. Liver function fluctuates depending on the virus's activity.
3. Liver Fibrosis	A condition in which the liver tissue becomes hard and fibrotic due to chronic inflammation. There are often no subjective symptoms in the early stages.
4. Liver Cirrhosis	Progression of fibrosis results in the loss of normal liver structure. Liver function declines significantly, and various complications may arise.
5. Hepatocellular Carcinoma (HCC)	It often occurs against a background of cirrhosis, But can also occur in conditions of chronic hepatitis and liver fibrosis. Regular screening is crucial for early detection.
6. Liver Transplant (if necessary)	One of the treatment options when liver function cannot be maintained due to end-stage cirrhosis or liver cancer progression.
(Note)	Not all individuals progress through this sequence. Some may remain in the asymptomatic carrier state for an extended period. Disease progression can be delayed with existing CHB therapies and other treatments.

***Notes on Statistical Data and Sources:**
The number of chronic hepatitis B (CHB) patients in China in this document is based on multiple public sources. Gyre Therapeutics estimates approximately 60 million as a lower-bound figure. A 2024 nationwide sero-epidemiological survey (n=91,869) estimates about 75 million based on an HBsAg positivity rate of 5.86%, while a 2024 WHO report estimates 79.7 million. As methodologies and population scopes differ, estimates range from approximately 60 to 80 million. Please refer to original sources for details.

F351: Bring New Hope to Life, Powering a Brighter Future for CHB Patients.

Updated on 14 August 2025

Estimated Peak Patient Population for F351: approximately 3.0 to 7.5 million[#] (based on GNI's own view)

1. Number of Hepatitis B Patients

Terms	Number of people	proportion
Population of China	1,411,100,000	-
Total number of HBV-positive persons	82,690,460	5.86%
Number of HBV-positive persons (exempted age deductions)	75,000,000	-9.30%

2. Hepatitis B patients with or without awareness of infection

Terms	Number of people	proportion
No awareness of infection	30,915,000	41.22%
Aware of infection	44,085,000	58.78%

F351, an anti-fibrotic agent, is planned to be used in combination with existing therapies

3. Number of patients under treatment with known infection

Terms	Number of people	proportion
Off-label for CHB therapies	2,645,100	6.0%
Indicated for CHB therapies, not receiving treatment	22,672,615	51.4%
Indicated for CHB therapies, under treatment	18,767,285	42.6%

F351 for patients with F2 or higher

4. Patients on treatment with an Ishak score of 2 or higher

Terms	Number of people	proportion
Ishak Less than 2	11,260,371	60.0%
Ishak 2 or higher*	**7,506,914**	**40.0%**

Survey results: published in 2024

a. Positive rate of recognized HBs antigen of infection estimated at **5.86%**
b. Only about **58.78%** of participants aged 15 years and older recognized their infection status
c. Of those who were aware of their own HBV infection status,
   1. **38.25%** are indicated for CHB therapy (increased to the current 94%)
   2. **17.33%** actually received CHB treatment

Tailwind from National Policy : 18 December 2022

The Chinese Society of Hepatology (CSH) and the Chinese Society of Infectious Diseases (CSID) have revised the *Guidelines for the Prevention and Treatment of Chronic Hepatitis B*, significantly lowering the threshold for initiating antiviral therapy to a detectable HBV DNA level (above 10–20 IU/mL). As a result of this revision, an estimated 94%(=51.4%+42.6%) of patients with chronic hepatitis B now meet the treatment eligibility criteria.

Note: The estimated patient population was calculated by GNI Group (August 2025). This forecast is subject to change depending on variations in the underlying assumptions used in the estimation.
[#]Souce: Prevalence of hepatic steatosis, fibrosis and associated factors in chronic hepatitis B
Journal of Clinical and Translational Hepatology, "Hydronidone treatment for liver fibrosis associated with CHB"

Estimated total number of patients treated by the “top three” products

Product Name	Key Manufacturer	Estimated Wholesale Value	Market Share	Estimated Retail Value	Market Positioning & Share Status	Recommended in China’s National Clinical Guidelines / Covered by Public Insurance	Annual Cost	Raw Materials
Fuzheng Huayu	Shanghai Huanghai Pharmaceutical (subsidiary of Baiyang Pharmaceuticals)	FY2024 (Full Year): CNY 631 million (+16.6% YoY) (approx. JPY 14.6 billion/ USD 94.7 million) H1 FY2025: CNY 371 million (+37.4% YoY) (approx. JPY 8.6 billion/ USD 55.7 million)	31.50%	Estimated CNY 1.6–2.1 billion (JPY 33.6–44.1 billion/ USD 240-315 million)	A core product of Shanghai Huanghai Pharmaceutical (a subsidiary of Baiyang Pharmaceuticals), with annual sales of approximately CNY 500 million (approx. JPY 10.5 billion/ USD 75 million). It is estimated to hold a top-tier market share of around 25–30% in China’s anti-liver fibrosis market. It has also completed U.S. FDA Phase 2 clinical trials and has a strong presence in hospital channels where scientific evidence is highly valued.	○	CNY 6,000–8,000 (approx. JPY 120,000–160,000/ USD 900-1,200)	Cordyceps sinensis mycelium (fungal biomass)
Biejia Ruangan Tablets (Biejia Ruangan)	Inner Mongolia Furui Medical	FY2024: approx. CNY 300 million (approx. JPY 7.0 billion/ USD 45.0 million) H1 FY2025: approx. CNY 150 million (+1.6% YoY) (approx. JPY 3.4 billion/ USD 22.5 million)	15%	Estimated CNY 0.8–1.0 billion (JPY 17.0–21.0 billion/ USD 120-150 million)	One of the two leading products alongside Fuzheng Huayu. First approved in China in 1999 for the treatment of liver fibrosis, it has established strong nationwide recognition and extensive prescription history. It holds a significant market share among antifibrotic traditional Chinese medicines in the hospital market in China.	○	CNY 12,000–14,000 (approx. JPY 250,000–290,000/ USD 1,800-2,100)	Turtle shell (Biejia)
Anluo Huaxian Pills (Anluo Huaxian)	Senlong Pharmaceutical	Approx. CNY 100 million (approx. JPY 2.3 billion / USD 15.0 million)	5%	Estimated CNY 0.2–0.3 billion (JPY 4.2–6.3 billion/ USD 30-45 million)	A key product following the top two. It is included in clinical guidelines and maintains a stable market presence.	○	CNY 4,000–5,000 (approx. JPY 80,000–100,000/ USD 600-750)	
Top 3 Products	**Top 3 companies**	**CNY 1.03 billion (JPY 23.8 billion/ USD 154.5 million)**	**51%**	**CNY 2.6–3.4 billion (JPY 54.8–71.4 billion/ USD 390-510 million)**				
Total Market	**Entire market**	**CNY 2.02 billion (JPY 46.7 billion/ USD 303.0 million)**	**100%**	**CNY 5.1–6.7 billion (JPY 107.5–140.0 billion/ USD 765-1,005 million)**				

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Estimated total number of patients treated by the “top three” products

Based on market data, it is estimated that approximately 0.4–0.6 million patients in China are effectively receiving treatment annually with three major traditional Chinese medicines. Given an estimated combined market share of around 50% for these leading products, **the total number of patients in China who are aware of liver fibrosis and are willing to pay out-of-pocket for treatment (cash payers) is estimated at a minimum of approximately 0.8–1.2 million**.

Differences across market reports are primarily attributable to whether figures are calculated on a cumulative basis or an annualized basis; for example, counting a patient who takes a product for three months as “one patient” versus “0.25 of a patient” can result in a fourfold difference in estimates.

	Fuzheng Huayu (Manufacturer: Shanghai Huanghai Pharmaceutical)	Biejia Ruangan Tablets	Anluo Huaxian Pills (Manufacturer: Huixian Anluo Huaxian Pharmaceutical)
Source	CMH, “China Liver Disease Drug Market Analysis Report	Company materials of Furuix (investor presentation) / securities firm research reports	Menet (Menet.com.cn), public hospital sales data
Annual Sales	CNY 1.2–1.6 billion *Note: FY2024. Sales in the first half of 2025 increased by 37% YOY.*	Approximately CNY 1.0–1.1 billion (primarily through hospital channels)	Approximately CNY 0.5–0.6 billion
Annual treatment cost	Approximately CNY 8,000–10,000 (approx. JPY 160,000–200,000/ USD 1,200-1,500)	According to reports, the standard cost for one course of treatment (3 months) is approximately CNY 1,500–2,000. The cost for a full year of treatment is approximately CNY 6,000–8,000. The figure of “JPY 250,000–290,000/ USD 900-1,200” represents the upper end based on retail pricing in the self-pay market. Reports reflecting reimbursement prices (e.g., VBP/centralized procurement) indicate a cost of around CNY 20 per day.	Approximately CNY 5,000–7,000
Estimated number of patients	Approximately 150,000–250,000	Approximately 150,000–200,000	Approximately 80,000–120,000

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F351 is expected to drive demand and establish a new market

Historically, in Western medicine, the treatment of chronic hepatitis B has been limited to "delaying" disease progression using antiviral agents, making the direct treatment of fibrosis itself highly challenging. If left unchecked, the disease progresses to irreversible liver cirrhosis and hepatocellular carcinoma. However, due to the lack of effective therapeutics, there are reported cases in clinical settings where physicians intentionally withhold the diagnosis of progressing fibrosis to spare patients from excessive psychological distress. This highlights a profound unmet medical need.

Currently, anti-fibrotic treatments primarily rely on Traditional Chinese Medicine (TCM). However, physicians trained in Western medicine, who prioritize rigorous objective data, have often hesitated to prescribe these treatments. In contrast, our therapeutic candidate, F351, has generated robust data demonstrating the "improvement of liver fibrosis" in a rigorous, placebo-controlled Phase 3 clinical trial. Backed by this compelling evidence, we anticipate capturing a new, expanding market by enabling those physicians who previously avoided TCM to confidently offer F351 as a viable treatment option.

Following approval, we will vigorously promote disease awareness campaigns to establish the understanding that "liver fibrosis is a treatable condition." Furthermore, we aim for F351 to be recommended as the "first-line therapy for anti-fibrosis" in the clinical guidelines issued by the Chinese Society of Hepatology. By establishing F351 as the standard of care, we anticipate making a significant contribution to the lives of many patients while simultaneously positioning the drug as a powerful pillar driving the sustainable revenue growth for GNI Group.

Traditional Chinese medicines primarily contribute through anti-fibrotic effects and immune modulation. By improving blood circulation in the liver (so-called “blood-activating” effects), they help prevent tissue stiffening and support tissue repair as an adjunctive therapy. It is estimated that approximately 80% of patients with chronic hepatitis B in China use some form of TCM in combination with other treatments.

Hepatology (2010 / the journal of the American Association for the Study of Liver Diseases) Lingyi Zhang / Contemporary Clinical Research of Traditional Chinese Medicines for Chronic Hepatitis B in China: An Analytical Review. "Despite the availability of IFN and/or nucleoside analogues, almost **80%** of the patients with CHB in China rely on TCM therapy."
⇒『BMJ Open』(2017)Tzung-Yi Tsai/Associations between prescribed Chinese herbal medicine and risk of hepatocellular carcinoma in patients with chronic hepatitis B: a nationwide population-based cohort study. “Owing to its low cost and low toxicity, about **80%** of patients with CHB in China and Taiwan have received CHM treatment”

Latest Guidelines for the Diagnosis and Treatment of Liver Fibrosis in China
The guidelines note that the penetration rate of traditional Chinese medicines (TCMs) for antifibrotic treatment remains “very low,” indicating a significantly underserved market. Globally, no Western medicines (chemically synthesized drugs) have yet been approved that can directly reverse or treat liver fibrosis. As a result, the Chinese guidelines strongly recommend TCM products such as Fuzheng Huayu, Compound Biejia Ruangan Tablets, and Anluo Huaxian Pills as first-line antifibrotic therapies.

Penetration rate among all chronic hepatitis B patients: less than 1%–2%
There are approximately 70–80 million chronic hepatitis B patients in China. While many patients receive antiviral therapies (e.g., entecavir), only a small fraction also use relatively expensive antifibrotic treatments.
Penetration rate among patients diagnosed with advanced fibrosis (treatment-eligible population): approximately 5%–10%
The number of patients with liver fibrosis or early-stage cirrhosis is estimated at approximately 7–10 million; however, fewer than 10% of these patients are receiving standard treatment with the recommended TCMs (defined as continuous use for several months or longer).
Total number of users of antifibrotic TCMs: approximately 0.35–1.0 million

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Number of Patients on Antiviral Therapy for Hepatitis B in China

According to studies by the China Center for Disease Control and Prevention (CDC) and the WHO-affiliated Polaris Observatory, it is estimated that **approximately 5–6 million patients** in China are receiving antiviral treatment for hepatitis B. A 2022 analysis estimated the number at **approximately 5.08 million**. In The Lancet Gastroenterology & Hepatology (October 2023), it is noted that "**only slightly more than 5 million patients are receiving treatment**."

Following the revision of the Guidelines for the Prevention and Treatment of Chronic Hepatitis B (2022 Edition) issued by the Chinese Medical Association, only three antiviral agents—entecavir (ETV), tenofovir disoproxil fumarate (TDF), and tenofovir alafenamide (TAF)—are recommended as first-line therapies (i.e., the standard treatments most strongly recommended for initial use).

Antiviral Therapy	ETV	TDF	TAF
Year of launch	2006	2014	2019
Annual cost at the time (JPY)	Approximately JPY 300,000/ USD 1,980	Approximately JPY 410,000/ USD 2,700	Approximately JPY 320,000/ USD 2,124
Annual cost at the time (CNY)	CNY 13,200	CNY 18,000	CNY 14,160
Pharmaceutical company	U.S.	U.S.	U.S.

While current Hepatitis B antivirals simply suppress viral replication within a highly competitive market (approximately 10 approved drugs in China), F351 is a therapeutic candidate aimed at directly treating and reversing advanced liver fibrosis. According to internal research, there are currently no globally approved therapies with proven efficacy in this field. F351 is being developed in China as a Class 1 New Chemical Drug and has officially received Breakthrough Therapy Designation.

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