



GNI Group Ltd.

Q2 FY2026 Financial Results Presentation

We Bring New Hope to Life

August 18, 2026

Securities Code: TSE:2160

Agenda

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3. Q2 FY2026 Segment Results

4. Appendix

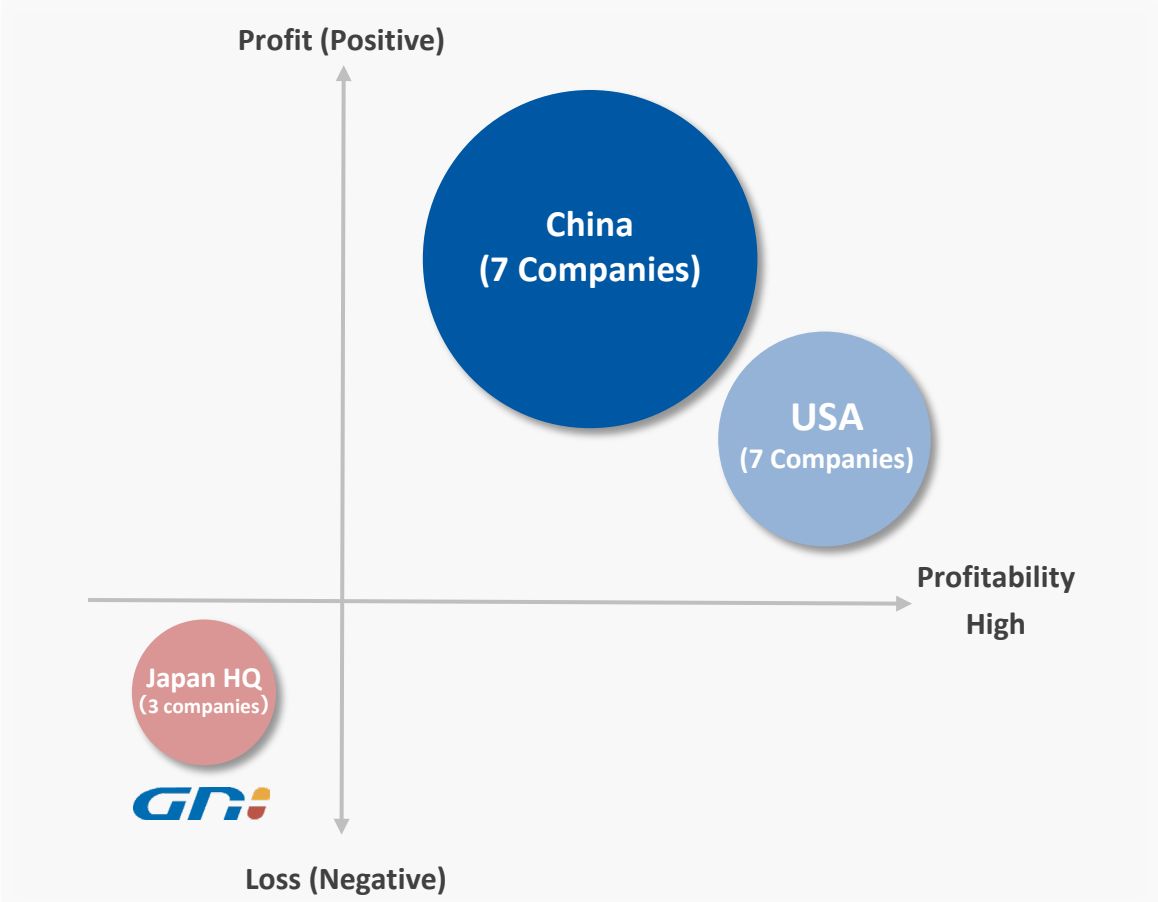
- 4.1 AYUMI Pharmaceutical Overview
- 4.2 F351

1.1 Toward a Second Founding Phase: Strategic Rational for the Acquisition

Pre-Acquisition Challenges: 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 Continued losses at the Japan headquarters due to the absence of revenue-generating businesses.



Eliminate the Structural Losses at the Japan Headquarters and Establish a Sustainable Earnings Base

Build a revenue-generating structure capable of covering headquarters costs and achieving profitability in the Japan business

July 1, 2026 Disclosure: Completion of the Acquisition of All Shares of AYUMI Pharmaceutical Holdings

Achieve Standalone Profitability and Cash Flow Generation at the Headquarters

Establish a structure in which the Japan business generates stable profits and cash flow, strengthening financial soundness and investment capacity

Reduce Dependence on Overseas Subsidiaries and Stabilize the Portfolio

Diversify the Group’s earnings base beyond the U.S. and China through monetization of the Japan business, building greater resilience to changes in the external environment.

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

AYUMI Pharmaceutical: Strategic Rationale and Transaction Validity

An acquisition combining a strong domestic business platform with clear strategic and financial rationale to accelerate growth across the Group

1. Strategic Rationale for the Acquisition of AYUMI Pharmaceutical (Synergies)

- ✓ **Strong Business Platform:** Establishes a solid healthcare and pharmaceutical business foundation in Japan
- ✓ **Stable Cash Flow Generation:** Establishes a source of stable, long-term cash flow in the Japanese market
- ✓ **In-Licensing Platform:** Provides a platform for the rapid introduction of promising overseas drugs into the Japanese market
- ✓ **Industry Network:** Establishes strong relationships with leading medical institutions and the pharmaceutical industry in Japan, enabling domestic out-licensing of the Group's proprietary pipeline
- ✓ **Revenue Growth Opportunities:** Provides sustained growth potential through pipeline expansion and the addition of new products

2. Rationale for the Transaction Terms and Execution

- ✓ **Rare Acquisition Opportunity:** A highly distinctive opportunity to acquire a business with development and manufacturing capabilities spanning both small-molecule drugs and biologics
- ✓ **Prudent Financial Management:** Financing is primarily debt-funded, with associated financial risks remaining manageable at the Group level
- ✓ **Reasonable Acquisition Consideration:** Fair and reasonable consideration in light of the underlying business value and expected cash flow generation

Completing the Global Platform with Japan as the Final Piece Linking the Group's U.S., China, and Japan Operations



**A Global Healthcare Value Chain Balancing Innovation,
Operational Efficiency, and Strategic Agility**

- ✓ GNI Group Headquarters / TSE-Listed Entity (TSE:2160)
 - ✓ Building a Globally Integrated Innovation Platform through Closer Collaboration
 - ✓ Active Collaboration across Group Companies
- ✓ Gyre Therapeutics / Nasdaq-Listed Entity (NASDAQ:GYRE)
 - ✓ Innovative Clinical Trials Planned to Support U.S. FDA Approval
 - ✓ Medtech Hub for Biomaterial Sales, R&D, and Manufacturing
 - ✓ R&D Hub for Next-Generation TPD / DAC Technologies
- ✓ Sales and Marketing Organization with a Strong Track Record of Commercialization
 - ✓ Leveraging PoC Studies in China to Optimize Development Timelines and Costs
 - ✓ GMP-Compliant Manufacturing Facilities



Launchpad for an Emerging Global Biopharma

Acquired ZooLabo, Merged GYRE and Cullgen, Acquired Ayumi, Rebuilding Medtech



Gyre Therapeutics

Global drug discovery and development powerhouse (NASDAQ: GYRE)



GNI Group

Group Company
(2160.T)

Ayumi Pharmaceuticals

Anchor for Japanese Healthcare Market



Medtech Group

Springboard to orthopedics and aesthetics markets

Global R&D and Strategic M&A Driven Expansion

6

Key Focus Areas: Fibrosis / Pain / Rheumatology / Oncology / Orthopedics / Aesthetic Medicine

~1,400

Global minded Employees

4

Operations Centered in China, the U.S., Japan, and Australia

30

Subsidiaries and Affiliates

Successful Track Record from Innovative Drug Discovery to Profitable Commercialization

38

Pipeline + Marketed Products

21,803+

Extensive Sales Network Covering Hospitals and Pharmacies in Japan and China

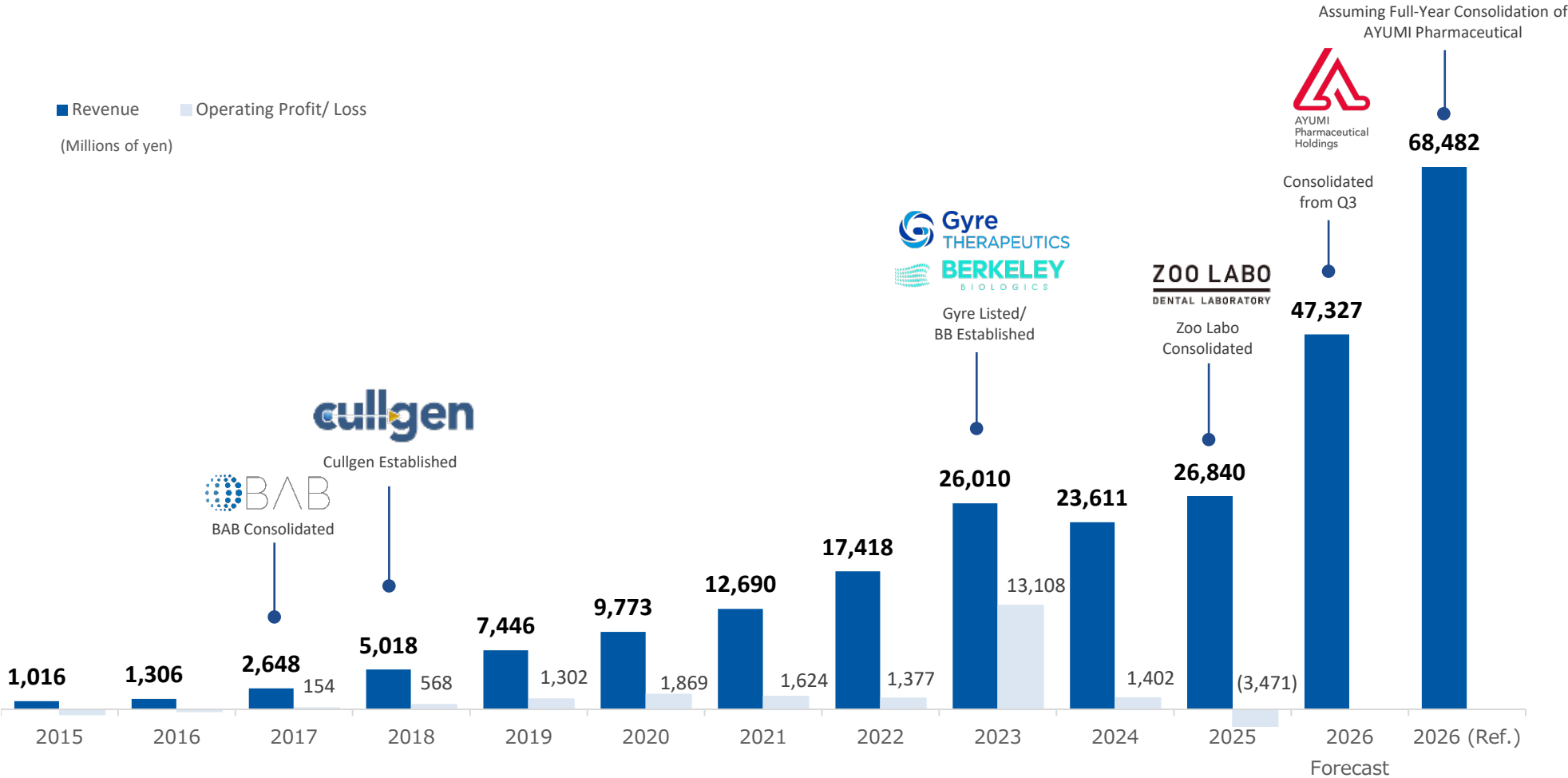
Pipeline

*The development details and schedule may change depending on future progress and other factors. In addition, the Ayumi Pharmaceutical product pipeline shown in the table below presents selected major products and does not cover all products.

Location	Product	Modality Target	Indication	Phase
PRC	F351 (Hydronidone)	Small molecule	CHB-Associated Liver Fibrosis	NDA
Global	F351 (Hydronidone)	Small molecule	MASH-Associated Liver Fibrosis	Phase 1
Global	CG001419	Degrader TRK	Acute and Chronic Pain	Phase 1
Global	CG001419	Degrader TRK	Solid Tumors	Phase 1
Global	CG009301	Degrader GSPT1	Leukemia and MYC+ cancers	Phase 1
Global	CG923308	Degrader CDK2	Breast cancer and multiple solid tumors	Pre-clinical
Global	CG620953	Degrader TYK2/ JAK1	Inflammatory Diseases	Pre-clinical
Global	Undisclosed	DAC Epigenetic Factor	Prostate, lung & bladder cancers	Discovery
Global	F528	Small molecule	Chronic Obstructive Pulmonary Disease (COPD)	Pre-clinical
Japan	Calonal® (Acetaminophen)	Small molecule	Pain, fever	Marketed
Japan	Etanercept BS	Biosimilar	Rheumatoid arthritis, etc.	Marketed
Japan	Adalimumab BS	Biosimilar	Rheumatoid arthritis, inflammatory bowel disease, etc.	Marketed
Japan	Iguratimod	Small molecule	Rheumatoid arthritis	Marketed
Japan	Tacrolimus (Tacrolimus Hydrate)	Small molecule	Rheumatoid arthritis, etc.	Marketed
Japan	Methotrexate	Small molecule	Rheumatoid arthritis	Marketed
Japan	Azulfidine® (Salazosulfapyridine)	Small molecule	Rheumatoid arthritis, etc.	Marketed
Japan	Rimatil® (Bucillamine)	Small molecule	Rheumatoid arthritis	Marketed
Japan	Tocilizumab BS	Biosimilar	Rheumatoid arthritis	Approved / preparing for launch
Japan	Ostabalo	Peptid	Orthopedics	Marketed
Japan	Bonoteo/Ricalbon	Small molecule	Orthopedics	Marketed
Japan	Undisclosed	Small molecule	Rheumatoid arthritis	Pre-filing
Japan	Undisclosed	Biosimilar	Pain / Orthopedics	Under filing
Japan	Undisclosed	Small molecule	Pain / Orthopedics	Pre-clinical
Japan	Undisclosed	Biosimilar	Other	Pre-filing
PRC	ETUARY™ (Pirfenidone)	Small molecule	Idiopathic Pulmonary Fibrosis (IPF)	Marketed
PRC	Pirfenidone	Small molecule	Pneumoconiosis	Phase 3
PRC	Pirfenidone	Small molecule	Radiation-Induced Lung Injury With or Without Immune-Related Pneumonitis	Phase 2/3
PRC	Pirfenidone	Small molecule	Dermatomyositis Interstitial Lung Disease (DM-ILD)	Phase 3
PRC	Pirfenidone	Small molecule	Systemic Sclerosis-associated Interstitial Lung Disease (SSc-ILD)	Phase 3
PRC	Pirfenidone	Small molecule	Diabetic Kidney Disease (DKD)	Phase 1
PRC	F573	Small molecule	Acute Liver Failure (ALF)/Acute-On-Chronic Liver Failure (ACLF)	Phase 2
PRC	F230	Small molecule	Pulmonary Arterial Hypertension (PAH)	Phase 1

Growth Trend Built around Three Core Businesses

Building a Foundation across Pharma, Biotech, and Medtech toward Becoming a Global Biopharma



1.2 Toward a Second Founding Phase: Group Synergies (Pain)

Pain: Overview of CALONAL

CALONAL is AYUMI Pharmaceutical’s proprietary brand
Sustained strong sales growth supported by distinctive product characteristics, strong competitive advantages, inclusion in treatment guidelines, and expanded indications

Business Profile

Acetaminophen (CALONAL)

- Widely used for fever and pain relief
- Strong brand recognition in Japan
- Brand awareness boosted by COVID-19 vaccine-related demand

Leading Brand

- Among the Highest Supply and Prescription Volumes in Japan
- Uses: Fever Reduction and Pain Relief

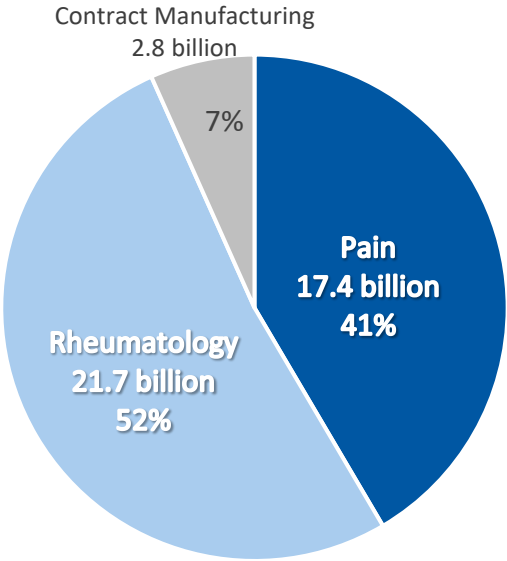
30+ Years of Continued Growth

- Growth supported by expanded dosing for pain
- Broad pain indications

Strong Support from Healthcare Professionals

- Wide range of strengths and dosage forms
- Established safety profile across a broad patient population

FY ended March 2026 Sales (JPY billion)



*Revenue figures are presented before elimination of intersegment sales, on a JGAAP basis.

Group Synergies in the Pain Management Field

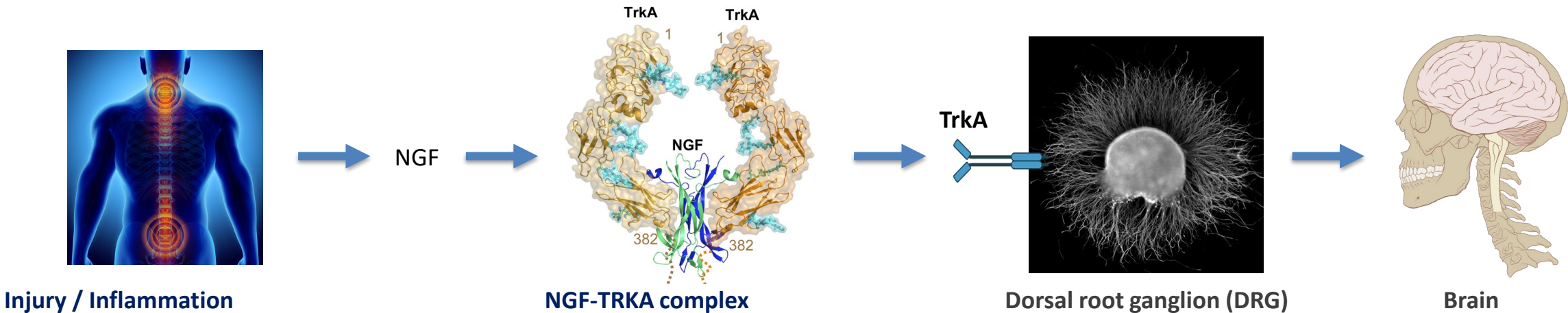
CG001419, a non-opioid, non-NSAID pain treatment candidate being developed by our Group, is expected to contribute to strengthening Ayumi Pharmaceutical’s product portfolio in the pain management field over the medium to long term.



	Opioids	NSAIDs	Cebranopadol	Journavx (Suzetrigine, VX-548)	VX-993	LTG-001	STC-004	CG001419
Safety Concerns	Risk to develop dependency	GI issues, headache, dizziness	Nausea	—	—	—	—	—
Effective	✓	Moderate	Moderate	Moderate	Did not meet acute pain primary endpoint	TBD	TBD	✓ Preclinical studies
MOA	Neuron hyperpolarization	COX inhibitor	Dual-NMR (NOP and opiate receptor) agonist First-in-class	Nav1.8 inhibitor First-in-class	Nav1.8 inhibitor Fast-follower	Nav1.8 inhibitor Fast-follower	Nav 1.8 inhibitor Fast-follower	TRK degrader First-in-class
Non-addictive	Rapid development (< 5 – 14 days)	✓	TBD	✓	✓	✓	✓	✓
Phase	Approved	Approved	Phase 3 Trials Complete	Approved	Discontinued as monotherapy for acute pain	Phase 1 Complete	Phase 1 Complete	Phase 1 Complete

The Role for TRKA in Nociception and Analgesia Has Been Validated in Humans

A. Nerve growth factor (NGF) stimulates the TrkA signaling pathway to transmit pain to the central nervous system



B. TRKA mutations cause congenital insensitivity to pain and anhidrosis (CIPA)

Sequencing of a cohort 78 CIPA patients

Mutations identified in: 22 genes

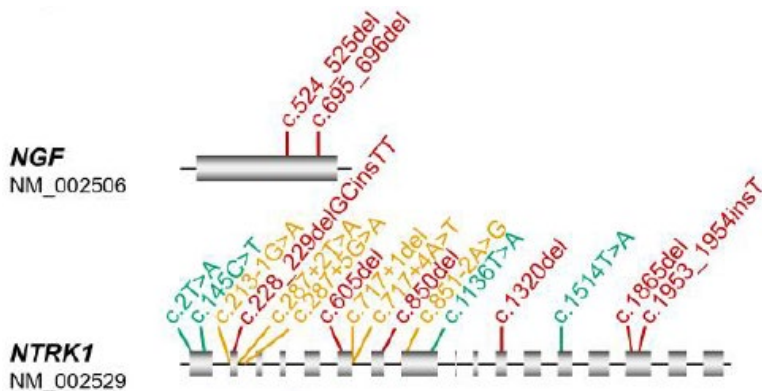
Mutation in *TRKA*: 20 patients

Mutation in *NGF*: 2 patients

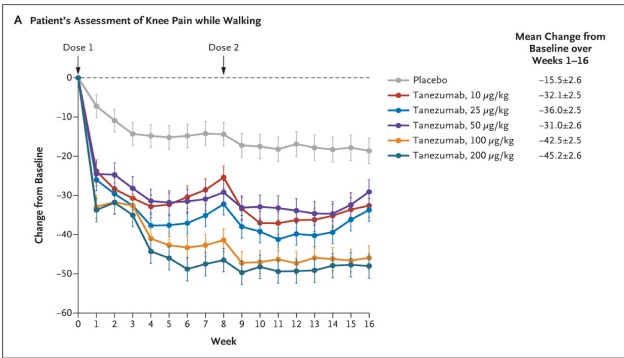
Mutation in *Nav1.7*: 22 patients

Other 19 genes: 34 patients

Indo et al (1996) *Nat Genet*. PMID: 8696348
Lischka et al (2023) *Brain* PMID: 37769650



C. Blocking NGF reduces osteoarthritis pain



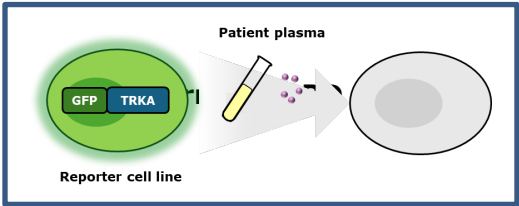
Lane et al. (2010) *NEJM* PMID: 20942668

Summary of Phase 1 PD, PK and Safety Study of CG001419

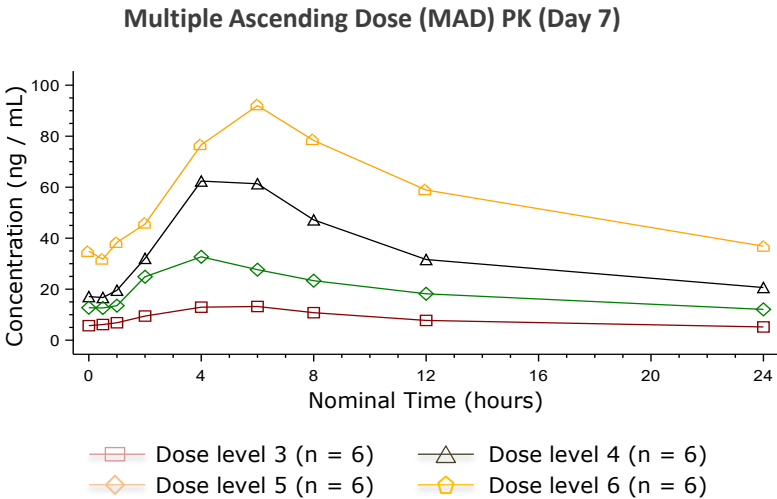
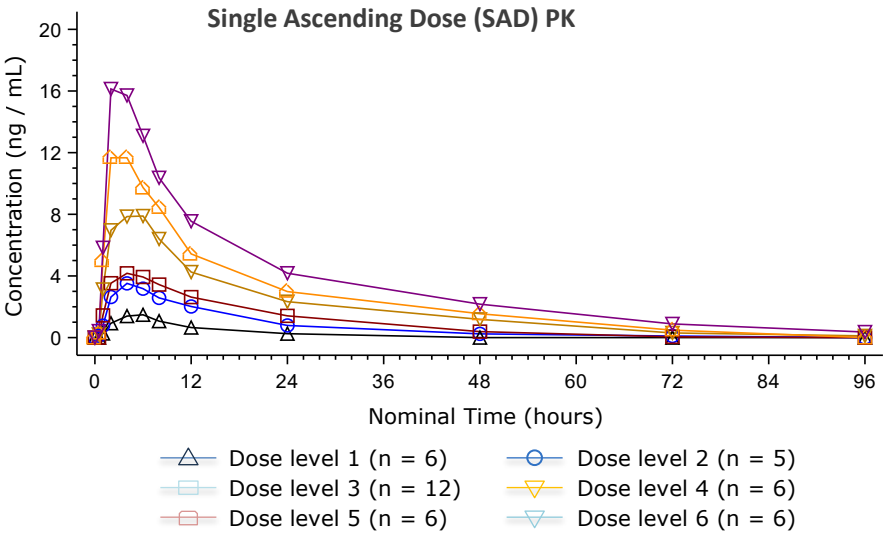
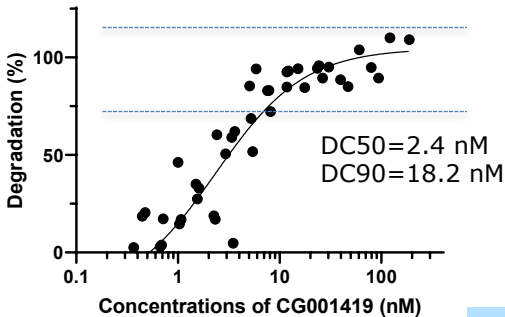
Well tolerated at all dose levels, with no drug-related serious adverse events reported ([announced on December 15, 2025](#))

CG001419-101 (NCT06636500): a SAD/MAD/FE study in healthy subjects in Australia

- The surrogate PD assay demonstrated DC₅₀ and DC₉₀ values of 2.4 nM and 18.2 nM, respectively
- Single and multiple oral doses of CG001419 up to the highest dosing levels were safe and well tolerated by the healthy subjects
- In the SAD/FE of the study, 72.2% had a TEAE and in the MAD 83.9% had a TEAE
- Most TEAEs were considered mild or moderate at their maximum severity in both parts of the study. No Grade 4 (potentially life-threatening) TEAEs were reported
- The most frequently reported TEAEs by SOC were general disorders and administration site conditions. Since the drug was administered orally, these were likely due to blood collection procedures
- Following a single oral dose, the exposure to CG001419 increased in a dose-proportional manner
- The food-effect cohort demonstrated a higher systemic exposure under the fed condition
- For the MAD cohorts after multiple daily dosing for 7 days, exposure to CG001419, metabolite M2 and M8 increased in a less than dose-proportional manner



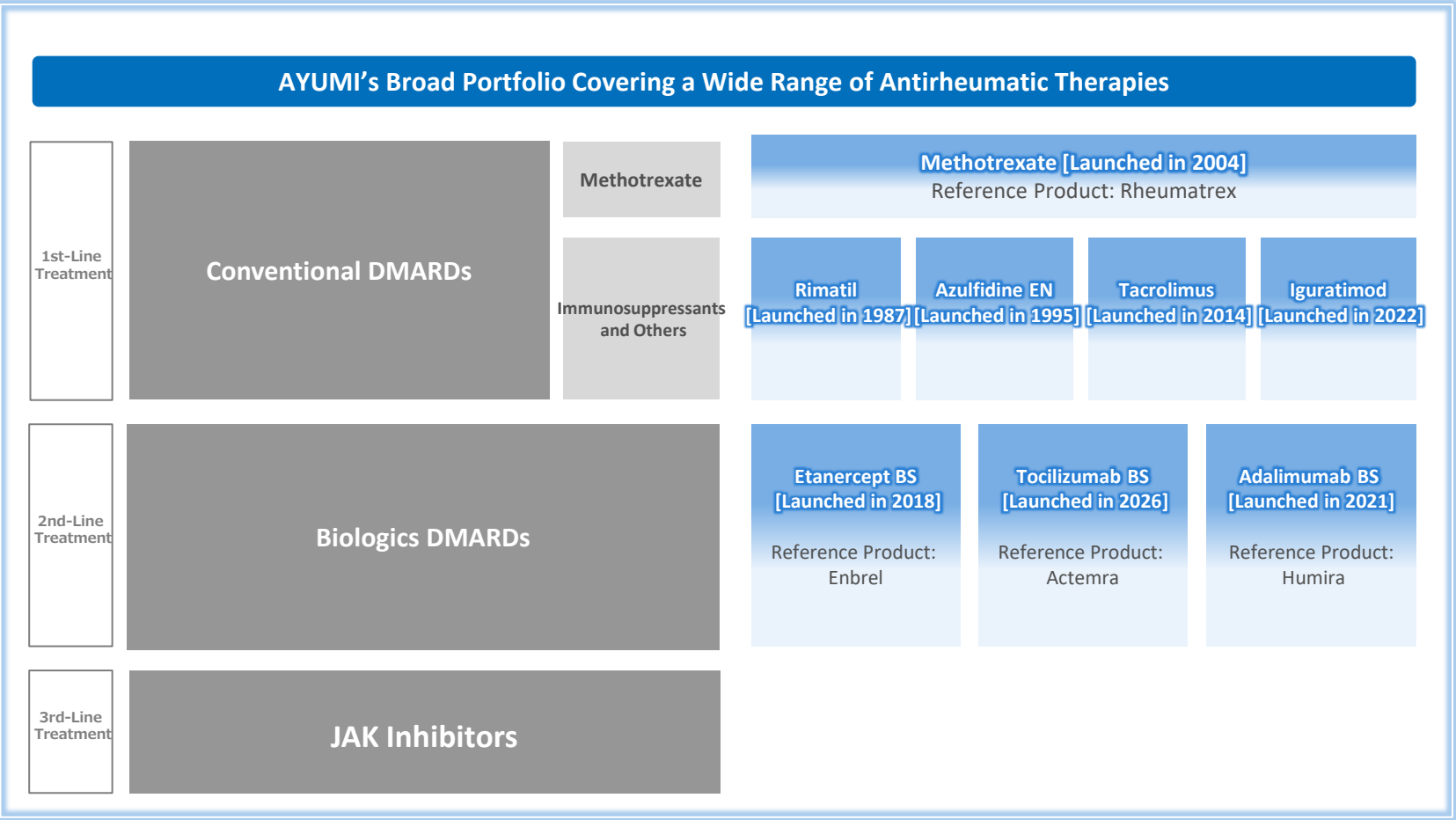
Clinical PD test



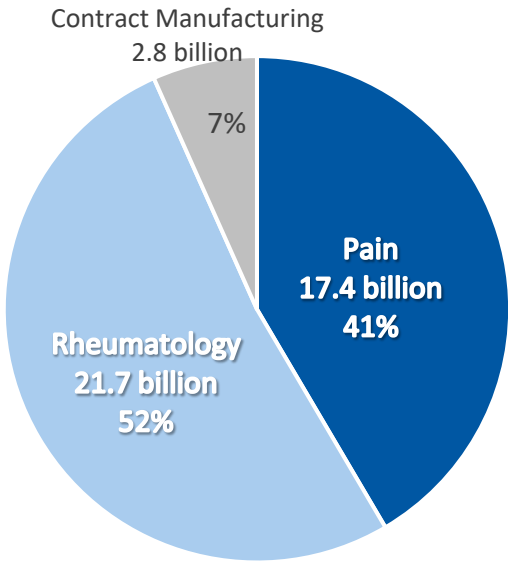
1.3 Toward a Second Founding Phase: Group Synergies (Rheumatism)

Strengths in Rheumatology

AYUMI Pharmaceutical has established strong sales capabilities across a broad network of hospitals and clinics through its extensive portfolio of antirheumatic drugs and comprehensive information support



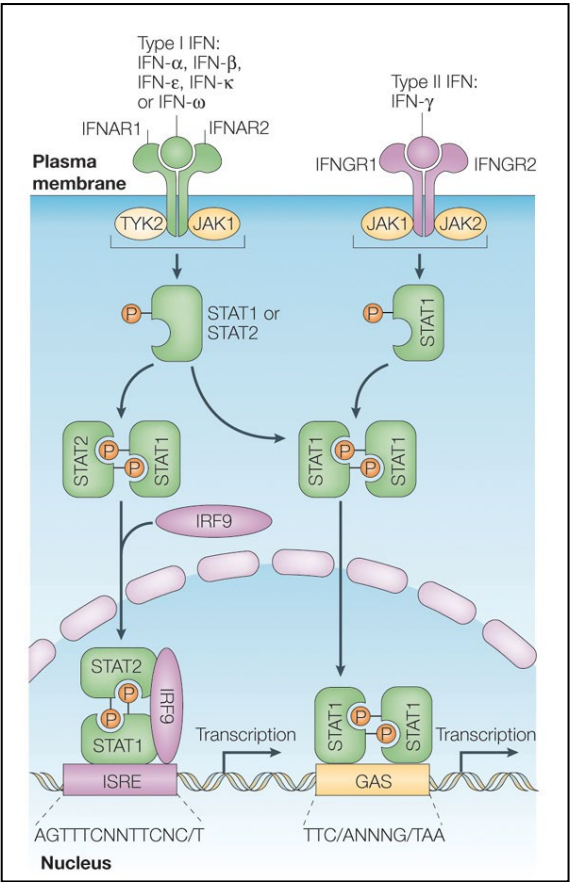
FY ended March 2026 Sales (JPY billion)



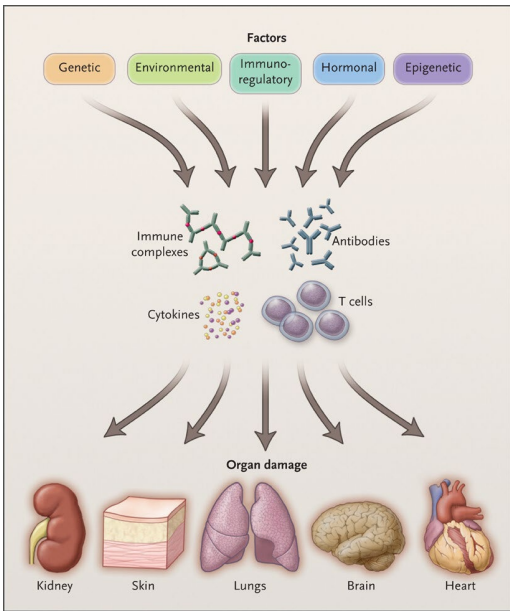
*Revenue figures are presented before elimination of intersegment sales, on a JGAAP basis.

Dual Targeting of TYK2 and JAK1 for Autoimmune Diseases, Focus on Systemic Lupus Erythematosus and Rheumatoid Arthritis

A. TYK2/JAK - STAT signaling

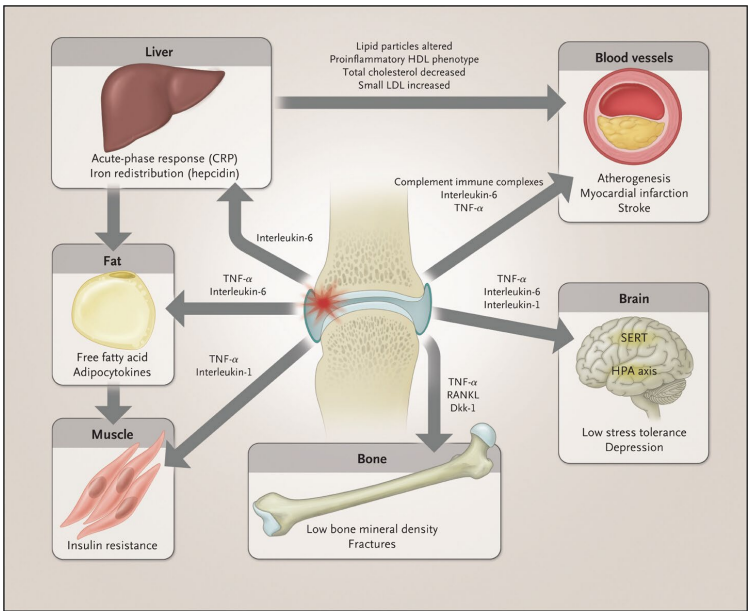


B. SLE Mechanism



Tsokos GC.(2011) *NEJM* PMID: 22129255

C. RA Mechanism



McInnes & Schett (2011) *NEJM* PMID: 22150039

Significant Opportunity

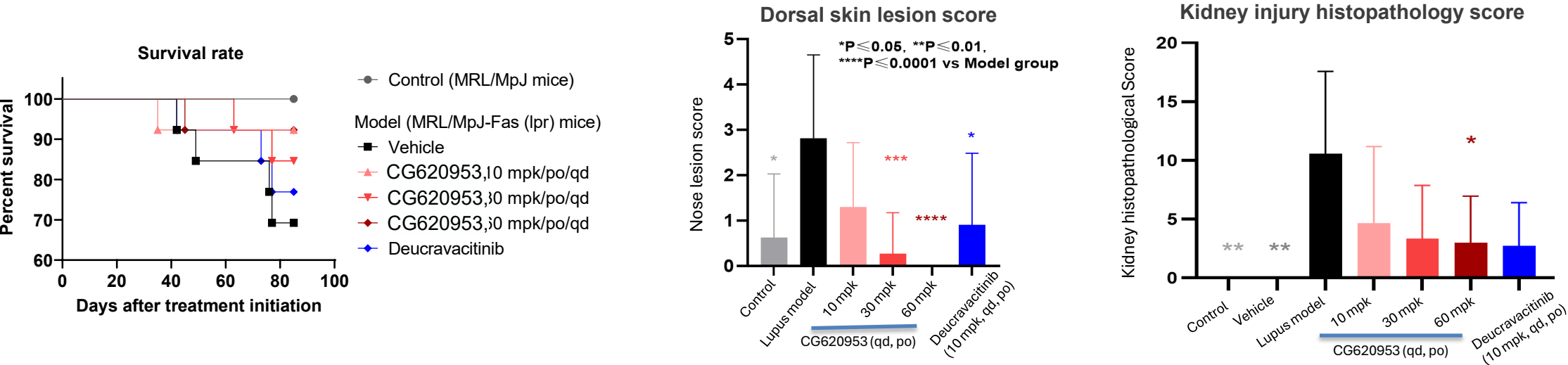
- 125,000,000 psoriasis patients worldwide¹
- 18,000,000 rheumatoid arthritis patients worldwide²
- ~204,000 lupus patients in the US in 2018³

Platanias, LC. (2005) *Nat Rev Immunol* PMID:15864272

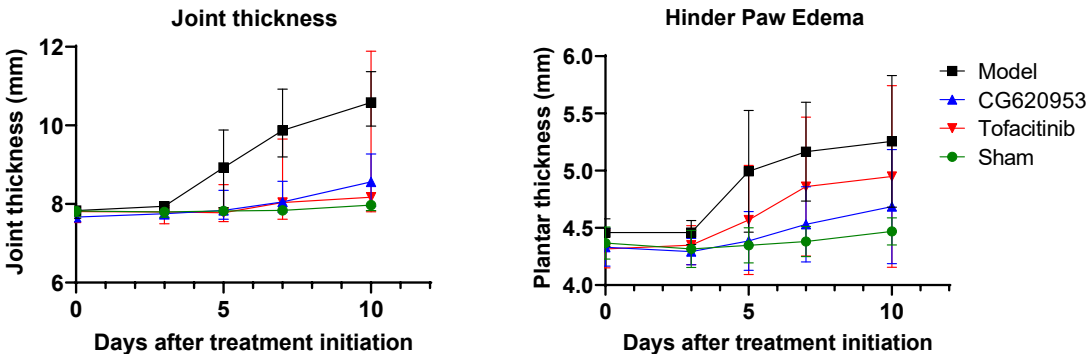
1. <https://www.psoriasis.org/psoriasis-statistics/>
2. <https://www.who.int/news-room/fact-sheets/detail/rheumatoid-arthritis>
3. <https://www.niams.nih.gov/health-topics/lupus/basics/symptoms-causes>

CG620953 Demonstrates Superior Efficacy in Preclinical Models of Lupus and Rheumatoid Arthritis (RA)

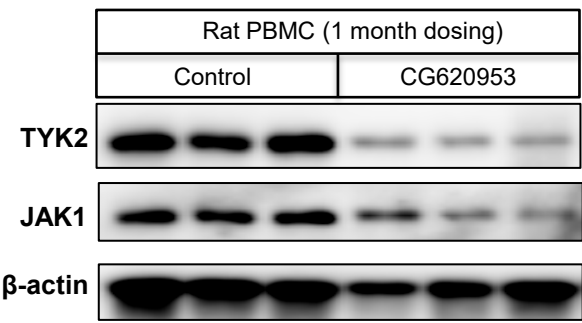
A. CG620953 is effective in a mouse model of systemic lupus erythematosus (SLE)



B. CG620953 shows efficacy in a rat model of rheumatoid arthritis



C. Targeted protein degradation in RA model



1.4 Toward a Second Founding Phase: Group Synergies (GNI Group BD Dept.)

GNI Group: Business Development Headquarters

GNI Group will take the lead in creating synergies through alliances across the Group

Establishing a Strong Medical and Pharmaceutical Platform in Japan

Industry Network

Build relationships with leading medical institutions and pharmaceutical companies in Japan to facilitate the domestic development and commercialization of our pipeline.

Growth Opportunities

Drive sustainable growth through pipeline expansion and the addition of new products.

Commercialization Platform

Establish a platform to rapidly introduce promising overseas drug candidates into the Japanese market.

2. Q2 FY2026 Financial Highlights

Q2 FY2026 Financial Highlights

JPY 500M Operating Profit Despite One-Time M&A and Restructuring Costs Foundation Set for Accelerated Growth from FY2027

- Operating profit was supported in part by a gain on reversal of accrued interest related to the integration, while acquisition-related expenses and upfront investments were also incurred.
- F351 has entered an important stage toward post-approval commercialization following the formal acceptance of its NDA.
- With the completion of the Gyre-Cullgen integration, we have established a growth platform in the U.S. integrating clinical development, drug discovery and commercialization.
- Ayumi Pharmaceutical will be fully consolidated from Q3, and the Group's top line is expected to expand significantly.

Consolidated Income Statement (Q2 YTD: January–June)

Despite the recognition of certain acquisition-related expenses for AYUMI Pharmaceutical in SG&A expenses, operating profit turned positive, supported by a gain on reversal of accrued interest related to Cullgen’s preferred shares

Millions of yen	2025 Q2	2026 Q2	Inc. / (Dec.)
Revenue	12,252	11,937	(315)
Gross profit	8,833	8,630	(203)
SG&A	7,995	11,420	3,425
R&D	1,596	2,124	528
Operating profit	(1,179)	534	1,713
Income before income taxes	(1,433)	(87)	1,346
Net profit	(2,342)	(588)	1,754
Profit attributable to owners of the parent	(915)	(1,988)	(1,073)

Selling, General and Administrative Expenses

- Advisory fees related to the acquisition of Ayumi Pharma: JPY 738M
- Expenses related to Gyre’s acquisition of Cullgen as a subsidiary: JPY 472M
- Share-based compensation expenses at Gyre: JPY 966M
- Share-based compensation expenses at Cullgen: JPY 144M

Research and Development Expenses

- R&D expenses related to Gyre’s preparation for the U.S. IND submission for F351: JPY 226M

Other Income and Other Expenses

- Gain on reversal of accrued interest: JPY 6,596M
- Impairment loss related to BB: JPY 667M

Segment

Millions of yen	Pharma		Biotech		Medtech		Others	
	2025 Q2	2026 Q2	2025 Q2	2026 Q2	2025 Q2	2026 Q2	2025 Q2	2026 Q2
Revenue	7,171	8,202	480	177	3,991	2,928	603	614
Operating profit	1,622	879	(2,274)	7,183	772	(1,837)	(1,704)	(4,954)

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

- Liabilities decreased significantly following Gyre's acquisition of Cullgen as a wholly owned subsidiary; changes in ownership interests resulting from intra-group reorganization altered the Group's capital structure.
- The capital structure is expected to change significantly from Q3 onward as AYUMI Pharmaceutical is consolidated into the Group.

Millions of yen	FY2024 Q4	FY2025 Q4	FY2026 Q2	Inc. / (Dec.)	
Total non-current Assets	42,720	43,057	46,125	3,068	
Goodwill	15,994	16,648	16,564	(84)	
Intangible assets	11,026	12,347	14,736	2,389	• F351 NDA Filing Costs and Progress in Phase 3c Development at Gyre Pharmaceuticals (see next page)
Total Current Assets	29,222	40,734	35,635	(5,098)	
Trade accounts receivable	6,236	8,056	6,347	(1,709)	• Steady Collection of Receivables Following Record-High Revenue at Gyre Pharmaceuticals
Inventories	2,529	3,752	4,129	377	
Cash and cash equivalents	10,115	21,101	17,164	(3,937)	
Total Liabilities	32,229	31,948	15,263	(16,685)	
Total non-current Liabilities	19,764	22,354	5,063	(17,291)	• JPY 16,825M in Cullgen preferred share liabilities (principal and accrued interest) was extinguished.
Total current Liabilities	12,464	9,594	10,200	606	
Total Equity	39,713	51,842	66,497	14,655	
Capital and Other Components of Equity	19,887	35,434	24,041	(11,394)	
Retained earnings	9,888	5,644	3,656	(1,988)	
Other Components of Equity	6,669	9,240	12,744	3,504	
Equity attributable to owners of the parent company to total assets	36,446	50,320	40,441	(9,879)	• Reclassification from equity attributable to owners of the parent to non-controlling interests due to changes in Gyre ownership.
Non-controlling Interests	3,267	1,522	26,055	24,533	• Reclassification of accrued interest on preferred shares from liabilities to equity. • Increase resulting from the issuance of new Gyre shares in connection with the acquisition of Cullgen as a subsidiary.

Consolidated Balance Sheet / Goodwill and Intangible Assets

An impairment loss of JPY 667 million was recognized following a review of future plans in anticipation of the restructuring of the Medtech business. The increase was mainly driven by higher capitalized development costs related to F351.

Breakdown		JPY Amounts (millions of yen)				Foreign Currency (Local Currency Basis)			
		FY2024 Q4	FY2025 Q4	FY2026 Q2	Inc. / (Dec.)	FY2024 Q4	FY2025 Q4	FY2026 Q2	Unit
Goodwill		15,994	16,648	16,564	(84)				
	Gyre Pharmaceuticals	188	194	207	13	8.7	8.7	8.7	Million RMB
	Gyre Therapeutics	7,616	7,535	7,815	280	48.1	48.1	48.1	Million USD
	Berkeley Advanced Biomaterials	6,653	6,584	6,830	246	42.1	42.1	42.1	Million USD
	Berkeley Biologics ①	1,230	1,217	593	(624)	7.8	7.8	3.7	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	14,736	2,389				
	Customer relationships ②	2,468	2,290	2,296	6	15.6	14.6	14.1	Million USD
	Brand (PPA)	69	63	62	(1)	0.4	0.4	0.4	Million USD
	Distribution rights ③	0	720	717	(3)	0	32.2	30.0	Million RMB
	Capitalized development costs	8,038	9,214	11,613	2,399				
	Gyre Therapeutics ④	4,745	4,696	4,871	175	30.0	30.0	30.0	Million USD
	Gyre Pharmaceuticals ⑤	3,293	4,517	6,742	2,225	152.0	202.0	282.4	Million RMB

- ① Berkeley Biologics Goodwill

JPY 667 million impairment loss recognized following a review of future plans in preparation for business restructuring.
- ② Customer relationships

Customer turnover over time at the acquired entity is recognized as amortization expense.
- ③ Distribution rights

Gyre Pharmaceuticals holds the sales rights for Etoel™ (nintedanib), which was launched in June 2025.
- ④ Capitalized development costs (Gyre Therapeutics)

Includes the rights held by Gyre Therapeutics related to F351 (actual development expenses are not included).
- ⑤ 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.

R&D expense

- R&D expenses increased YoY 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 Gyre Pharmaceuticals, reflecting NDA-related expenses for the commercialization of F351 and progress in the Phase 3c trial

	FY2023 Actual	FY2024 Actual	FY2025 Actual	FY2025 Q2	FY2026 Q2
Millions of yen					
Consolidated R&D expenses	2,557	2,811	3,298	1,596	2,124
Capitalized development costs	940	1,165	1,176	(92)	2,399
Total	3,497	3,976	4,474	1,502	4,523

FY2026 Consolidated Earnings Forecast

Consolidated Results: Revenue from AYUMI Pharmaceutical for the second half of FY2026 to be reflected in the Pharmaceutical segment

Millions of yen	FY2024 Actual	FY2025 Actual	FY2026 Previous Forecast Announced Mar. 31, 2026	FY2026 Revised Forecast Announced Aug. 14, 2026	
					Revision
Consolidated Revenue	23,611	26,840	27,158	47,327	+20,169
Pharma	15,847	17,314	*16,000	*40,622	+24,622
Biotech	1,439	789	544	177	(367)
Medtech	5,189	7,584	9,674	5,647	(4,027)
Other	1,156	1,169	940	881	(59)

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

Profit Items

① R&D expenses in Biotech business	The outlook is currently under review, as the scale of clinical trials and timing of regulatory approvals, which depend on decisions by regulatory authorities such as the FDA, remain uncertain, in addition to future R&D progress and developments.
② Upfront Investment Associated with F351 Approval	The outlook is currently under review, as whether, when and to what extent upfront investments will be made in anticipation of approval remain uncertain and are highly dependent on the timing of regulatory approval.
③ Costs Related to the Acquisition of Ayumi Pharmaceutical	Total costs are expected to be approximately JPY 2,437M, including advisory fees (financial advisory, business, legal, financial and tax due diligence, and contract-related fees), share issuance costs and other expenses.JPY 738M was recognized in Q2 2026.

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

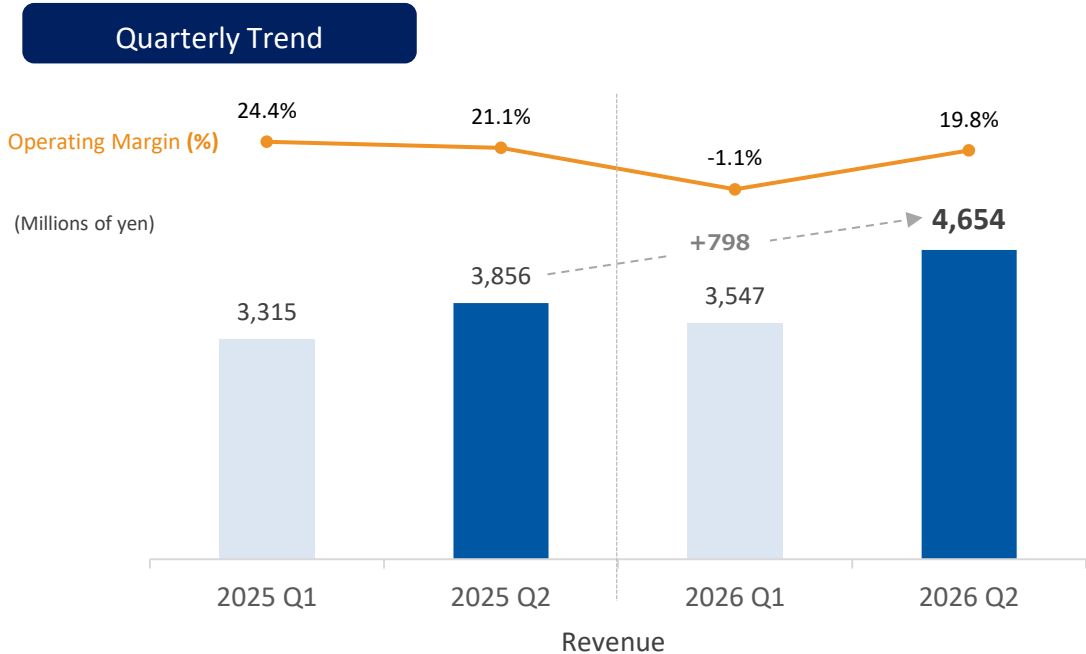
3. Q2 FY2026 Segment Results

Pharma

Financial Results

(Millions of Yen)	FY2021 Actual	FY2022 Actual	FY2023 Actual	FY2024 Actual	FY2025 Actual	FY2025 (Quarterly)	FY2026 (Quarterly)	Inc. /(Dec)	FY2026 Forecast
						Q2	Q2		
Revenue	9,868	13,346	15,742	15,847	17,314	7,171	8,202	1,031	*40,622
Operating Profit	2,501	3,735	4,054	4,003	3,213	1,622	879	(744)	—
Operating Margin	25.3%	28.0%	25.8%	25.3%	18.6%	22.6%	10.7%		

Financial Summary: Revenue Increased 14% YoY, with Q2 Operating Margin Recovering to Approximately 20%



- **Revenue: JPY 8,202M (+14.3% YoY)**
 - Q2 revenue reached a record high, driven by solid sales of ETUARY™ and favorable foreign exchange effects.
 - Promotional activities continued from Q1 also contributed to revenue growth.
- **Operating Profit: JPY 879M**
 - Share-based compensation expense (H1 cumulative): JPY 966 million
Expense recognized on a pro-rata basis for share-based awards granted in the prior fiscal year by Gyre and Gyre Pharmaceuticals to their directors, officers and employees.
- **Outlook for the Second Half**
 - Pharmaceutical business revenue forecast revised from JPY 16,000M to JPY 40,622M , reflecting AYUMI Pharmaceutical’s second-half results
 - F351 is currently under priority NDA review but is excluded from the forecast based on a conservative assumption

*Includes GNI Group’s own interpretation.

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.

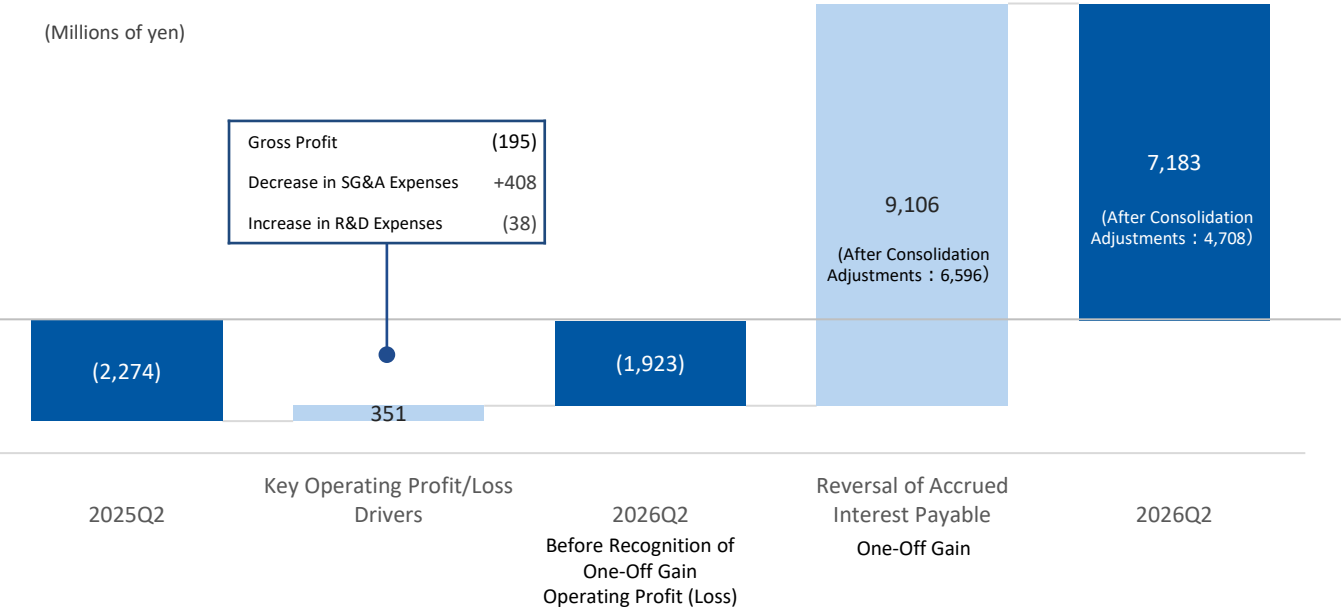
Biotech

Financial Results

(Millions of Yen)	FY2021 Actual	FY2022 Actual	FY2023 Actual	FY2024 Actual	FY2025 Actual	FY2025 (Quarterly) Q2	FY2026 (Quarterly) Q2	Inc. /(Dec)	FY2026 Forecast
Revenue	0	0	5,805	1,439	789	480	177	(303)	*177
Operating Profit	(1,920)	(2,794)	2,374	(3,371)	(3,958)	(2,274)	7,183	9,457	—

Financial Summary:Returned to Profitability Due to Gain Recognized in Connection with the Integration of Gyre and Cullgen

Changes in Operating Profit (Loss)



- Revenue**
Revenue decreased following the termination of the research collaboration agreement with Astellas Pharma.
- Gain on reversal of accrued interest: JPY 9,106M**
Recognized in connection with the integration of Gyre and Cullgen. After eliminating JPY 2,510M in intercompany transactions upon consolidation, the gain recognized on a consolidated basis was JPY 6,596M, resulting in consolidated operating profit of JPY 4,708M.
- Operating Loss Excluding Gain on Debt Forgiveness: JPY 1,923M**
Improved by JPY 351M YoY. Expenses incurred in the prior-year period in preparation for Cullgen’s standalone listing did not recur. R&D expenses remained broadly in line with the prior year at JPY 1,202M.
- Elimination of Related Finance Costs**
Accrued interest previously recognized each period was extinguished and accounted for as part of the gain on debt forgiveness. No further interest expense related to this debt will be incurred from the current fiscal year onward, contributing to an improvement in profit before tax. (Prior-year finance costs: JPY 1,473M)

Major Pharmaceutical & Drug Discovery of Gyre (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)

Etores™

(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
- NDA accepted for review on May 13, 2026, with priority review designation.

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 in 2026.

* based on GNI’s own view

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
- A Phase 2 trial is planned in cancer-induced bone pain (CIBP) or other pain syndromes associated with metastatic cancer.

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

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>

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: ~125 million²
 - Rheumatoid arthritis patients: ~18 million³
 - U.S. SLE patients (2018): ~204,000⁴
- Phase 1 IND submission planned in the U.S. and/or China in Q1 2027

CG923308 (Breast cancer and multiple solid tumors)

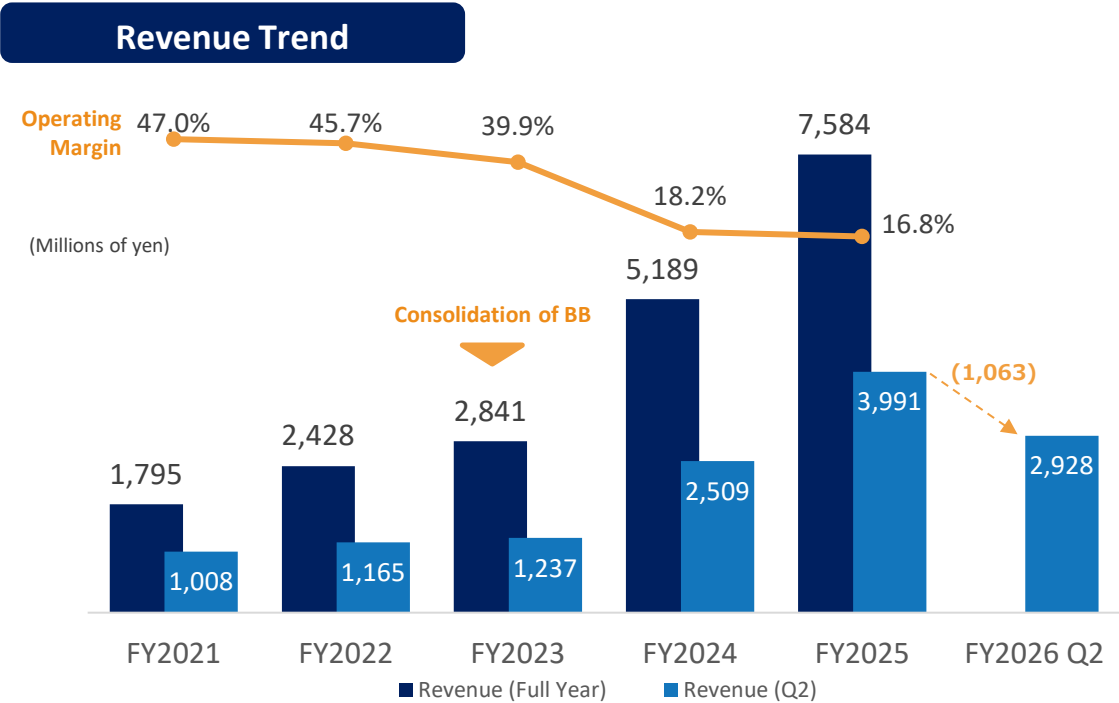
- A dual degrader that selectively and potently degrades both CDK2 and Cyclin E.
- Phase 1 IND submission planned in the U.S. and/or China in Q1 2027

Medtech

Financial Results

(Millions of Yen)	FY2021 Actual	FY2022 Actual	FY2023 Actual	FY2024 Actual	FY2025 Actual	FY2025 (Quarterly)	FY2026 (Quarterly)	Inc. / (Dec)	FY2026 Forecast
						Q2	Q2		
Revenue	1,795	2,428	2,841	5,189	7,584	3,991	2,928	(1,063)	*5,647
Operating Profit	844	1,110	1,133	942	1,274	772	(1,837)	(2,610)	—

Financial Summary: Temporary Demand Drop-Off Weighs on Revenue; Medtech Restructuring Under Review



- **Revenue: JPY 2,928M (YoY: down JPY 1,063M)**
 - Despite the positive revenue contribution from ZOO LABO, revenue declined as it was insufficient to offset the normalization of one-time demand in the biomaterials business ahead of U.S. Medicare changes.
- **Operating Loss: JPY 1,837M (YoY: down JPY 2,610M)**
 - The impact of U.S. Medicare changes on BB also weighed on profitability
 - Continued upfront investment in private-label products scheduled for launch in the second half
 - JPY 667 million impairment loss recorded for BB
- **Outlook for the Second Half**
 - Shift from a scale-driven strategy to a differentiation-focused approach; revenue forecast revised from **JPY 9,674M to JPY 5,647M**
 - Considering business restructuring centered on the transition to a private-label model and global niche manufacturing and commercialization in medical aesthetics
 - BAB’s private-label products and medical aesthetics clinical programs are both expected to receive regulatory approval in Q4 in the U.S. and China

[*August 14, 2026 Disclosure: Revision to Full-Year 2026 Financial Forecast](#)

Medtech: Company-Wide Resource Optimization for the Second Founding Phase

— Strategic Shift from “Quantity to Quality”

With the consolidation of AYUMI Pharmaceutical, Medtech’s share of Group revenue will effectively decline to approximately 8%. This share is expected to decline further as the GNI Group’s anticipated new drugs are launched, creating an opportune time to reassess the allocation of management resources. The Group is therefore optimizing its overall business portfolio.

The Medtech business will move away from its previous strategy focused on expanding sales volume and shift toward higher-value products and establishing leading positions in global niche markets. Through this qualitative transformation, the business will be restructured toward a higher-margin model.

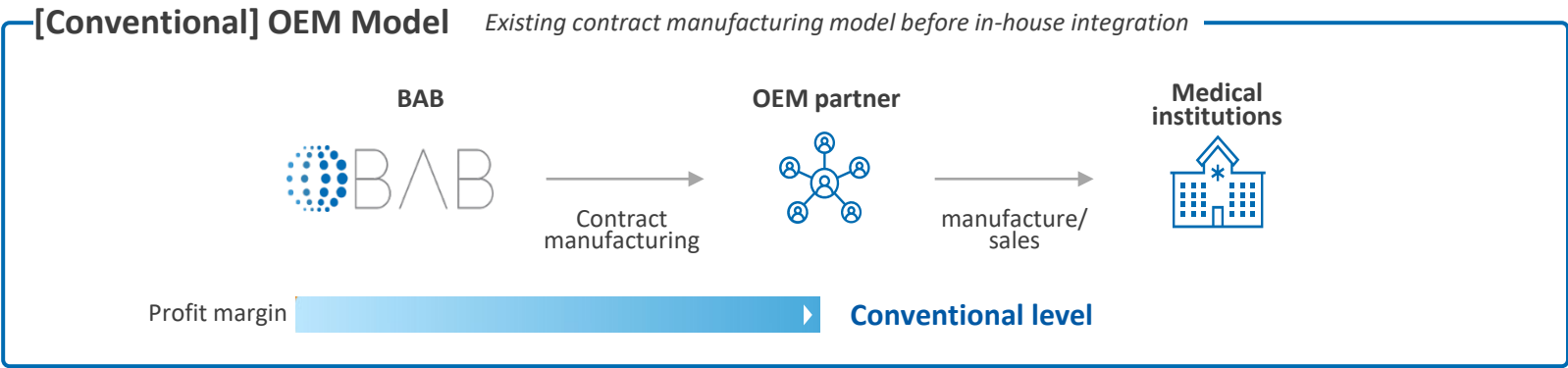
	FY2021	FY2022	FY2023	FY2024	FY2025	FY2026 Forecast	FY2026 Illustrative
Medtech Revenue (Millions of yen)	1,795	2,428	2,841	5,189	7,584	5,647	5,647
Group Revenue (Millions of yen)	12,690	17,418	26,010	23,611	26,840	47,327	68,482
Share of Group Revenue (%)	14.1%	13.9%	10.9%	22.0%	28.3%	11.9%	8.2%

AYUMI Pharmaceutical Consolidated from Q3
Assuming Full-Year Consolidation of AYUMI Pharmaceutical

The Medtech Group’s First Proprietary Brand Strategic Product

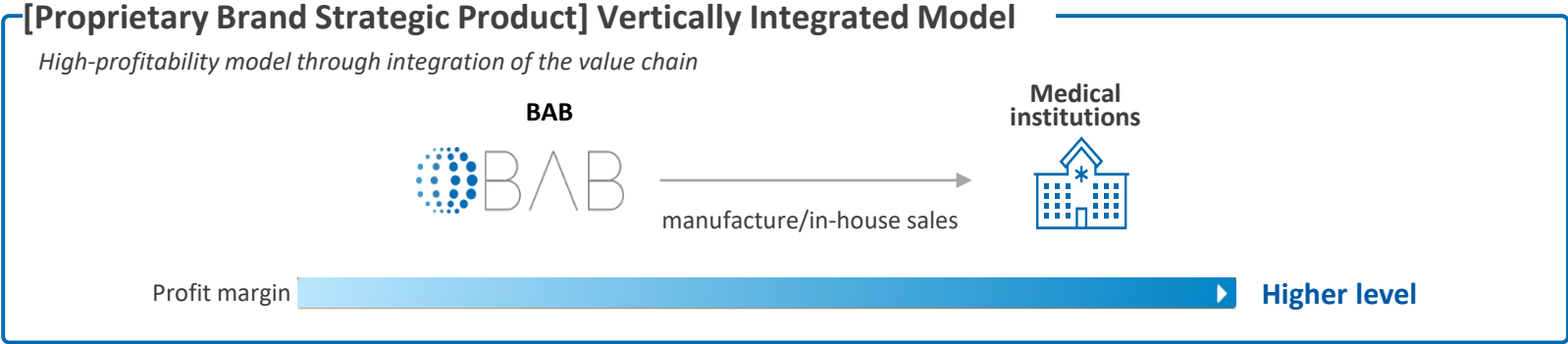
Sales of private-brand (PB) products based on the Group’s aim to establish an in-house manufacturing and sales framework

- 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.



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 the Medical Aesthetics Market through OsDerma

DermiraCa® Developed by OsDerma

Aiming to Expand Market Share and Establish a Strong Brand in the Premium Medical Aesthetics Market

- An injectable containing hydroxyapatite (HAp), a major component of bone and teeth, with high biocompatibility and biodegradability
- Promotes tissue repair and collagen regeneration, with safety and efficacy demonstrated in clinical studies
- Combines immediate effects with sustained regenerative benefits

Exhibit 1 - Medical Aesthetics Is Projected to Continue Its Strong Growth



Sources: American Society of Plastic Surgeons; American Med Spa Association; Clarivate; BCG proprietary provider survey; BCG analysis.
Note: Estimates could change depending on market conditions.

Competitive Advantages

Tighter Regulation of Off-Label Use in Medical Aesthetics Expected to Provide a Tailwind

- ① Synergies with the Medtech Group
 - Validation of competitive functional biomaterials
 - Potential for high margins through vertically integrated production, from raw materials to manufacturing, including in-house development of manufacturing equipment
- ② Synergies with the drug discovery group
 - Extensive clinical trial experience, providing an advantage over peers with limited clinical development capabilities
 - Established network of leading clinical investigators and hospitals
- ③ Group Financial Strength
 - Peers typically require external financing to conduct clinical trials

Progress

A multicenter clinical trial is currently underway under the leadership of Professor Luo Shengkang, a renowned plastic surgery specialist in China, in collaboration with six leading medical institutions, including Peking Union Medical College Hospital. A total of 163 subjects have been enrolled, and the trial is expected to be completed around November 2026. Subject to confirmation of efficacy and safety, an application for marketing approval is planned to be submitted to the NMPA in Q1 2027.

Note: OsDerma Medical, Inc. is an equity-method affiliate in which the Company holds a 20% equity interest.
Source: iResearch (converted into JPY by the Company)

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

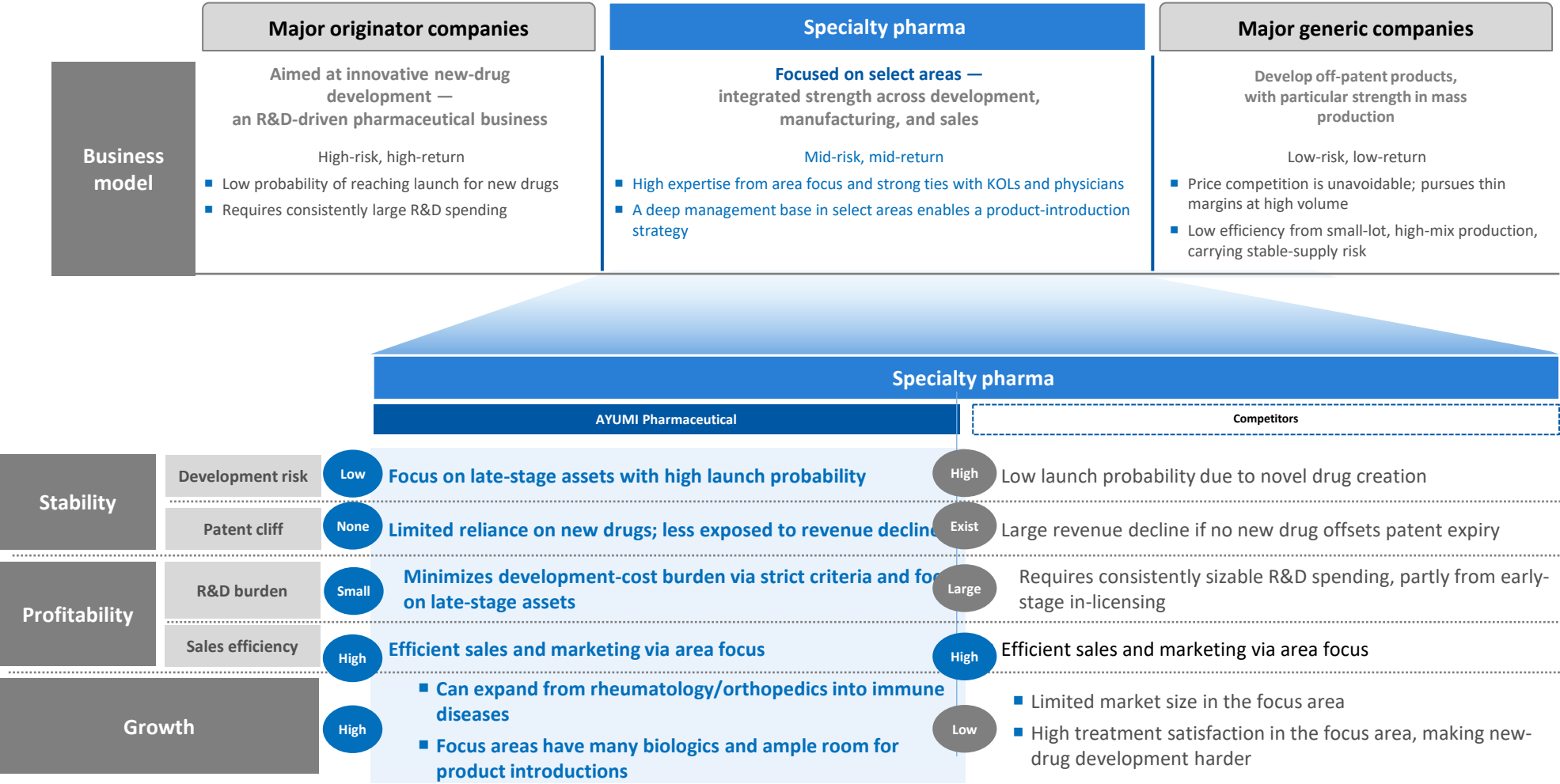
Millions of yen	Q2 2025	Q2 2026	Inc. / (Dec.)	Factors for increase/decrease
Revenue	603	614	11	
Operating profit/ Loss	(1,704)	(4,954)	(3,250)	
GNI Group	(940)	(2,443)	(1,503)	• Advisory fees related to the acquisition of Ayumi Pharmaceutical: JPY 738M • Reversal of accrued interest on Cullgen preferred shares: JPY 1,038M (fully eliminated on consolidation as an intercompany transaction)
Gyre Therapeutics	(529)	(1,499)	(970)	• Acquisition-related expenses for Cullgen, including legal fees: Approx. JPY 472M • MASH-related R&D expenses: JPY 226M
GNI USA	(65)	(1,436)	(1,371)	• Reversal of accrued interest on Cullgen preferred shares: JPY 1,280M (fully eliminated on consolidation as an intercompany transaction)
Other 11 companies	(170)	424	594	

Note: Calculated based on IFRS.

4.1 Appendix: AYUMI Pharmaceutical Overview

Business model

A specialty pharma that has built an efficient business model by focusing on select therapeutic areas
Efficient investment in late-stage assets under strict criteria delivers outstanding stability and profitability

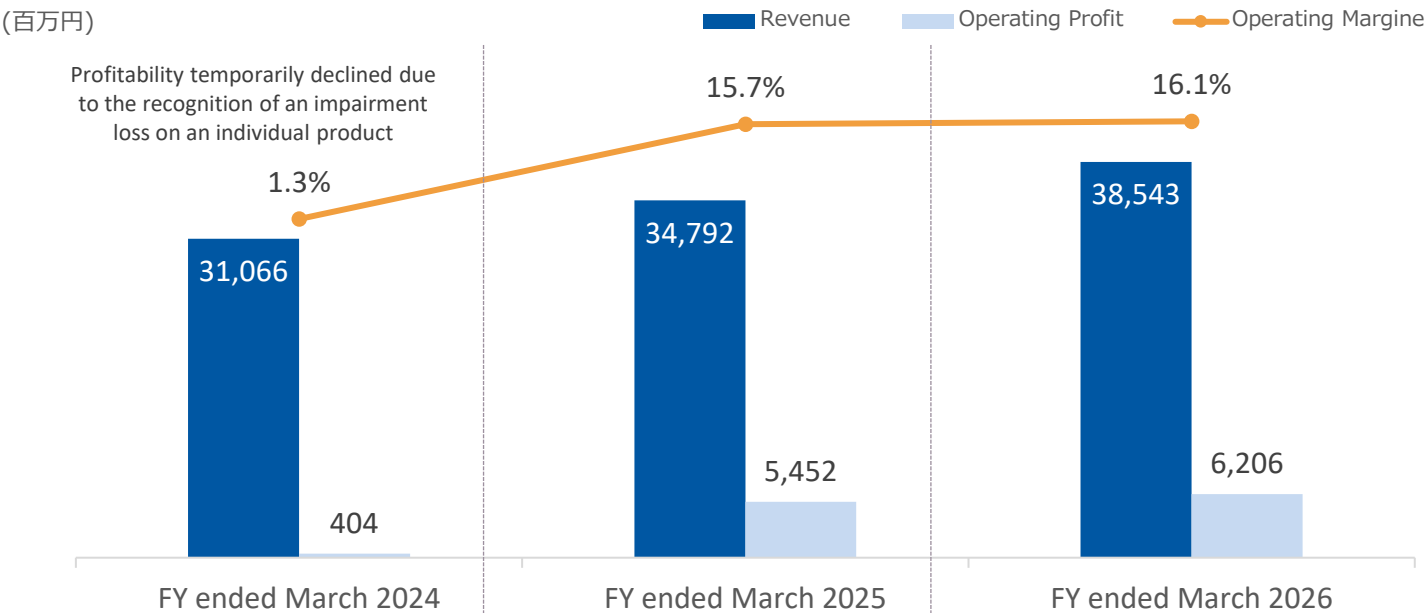


FY2026 Consolidated Earnings Forecast – Ayumi Pharmaceutical



Ayumi Pharmaceutical’s stable earnings base to contribute from H2 2026 (Q3 onward)

Ayumi Pharmaceutical – 3-Year Financial Performance*



(JPY million)	FY ended Mar. 2024	FY ended Mar. 2025	FY ended Mar. 2026
Total Assets	116,798	115,014	109,031
Total Liabilities	90,450	86,066	76,861
Total Equity	26,347	28,947	32,170

Growth Strategy



- 1 Introducing GNI’s existing products and pipeline to the Japanese market
- 2 In-licensing opportunities within the GNI’s network
- 3 F351 Launch + Pipeline Advancement

* Revenue figures for Ayumi Pharmaceutical for FY2024 through FY2026 shown on this slide are presented in accordance with IFRS. As a result, they differ from JGAAP-based net sales before deduction of sales rebates.

4.2 Appendix: F351

**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.

[#]Source: [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)				

All statements herein represent GNI’s own interpretations and may differ from the views of Gyre Therapeutics. This material contains market forecasts, which are subject to various risks and uncertainties, and actual results may differ materially.

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 <i>Note: FY2024. Sales in the first half of 2025 increased by 37% YOY.</i>	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.”**

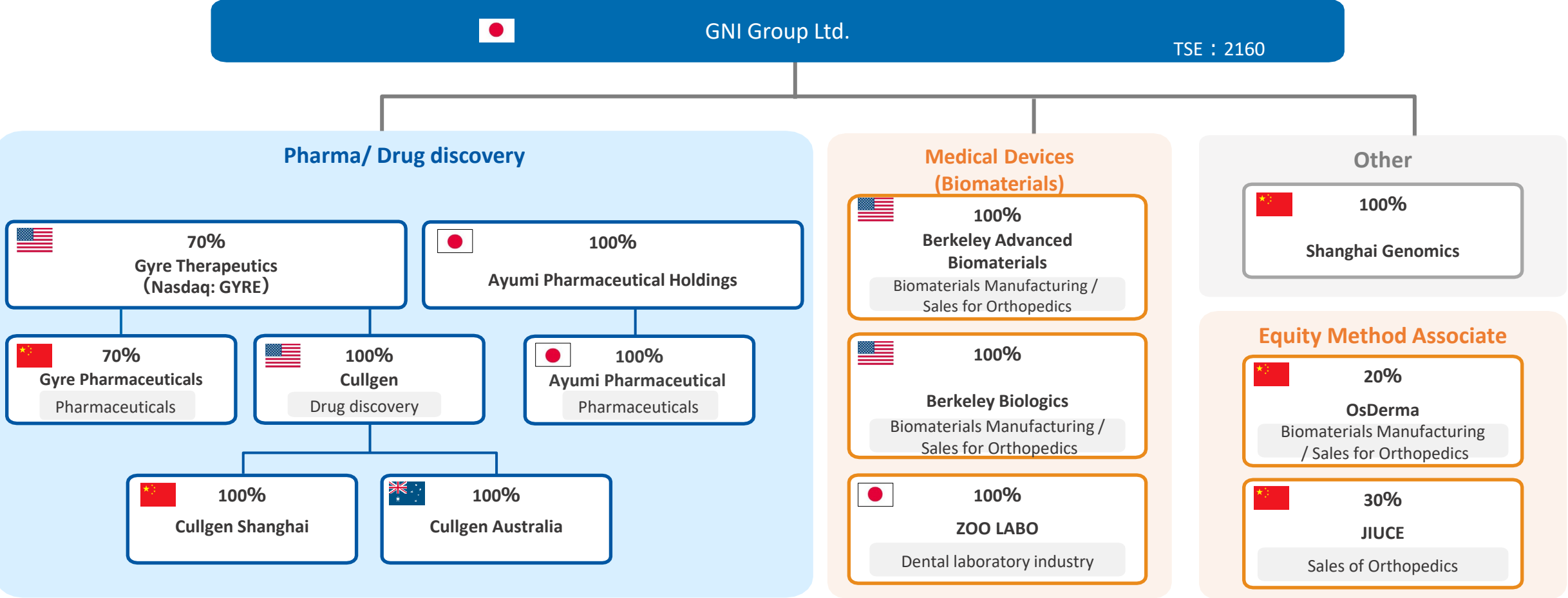
Following the revision of the Guidelines for the Prevention and Treatment of Chronic Hepatitis B (2022 Edition) issued by the Chinese Medical Association, only three antiviral agents—entecavir (ETV), tenofovir disoproxil fumarate (TDF), and tenofovir alafenamide (TAF)—are recommended as first-line therapies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

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