



GNI Group Ltd.

FY2025 Full Year Financial Results Corporate Presentation

We Bring New Hope to Life



**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

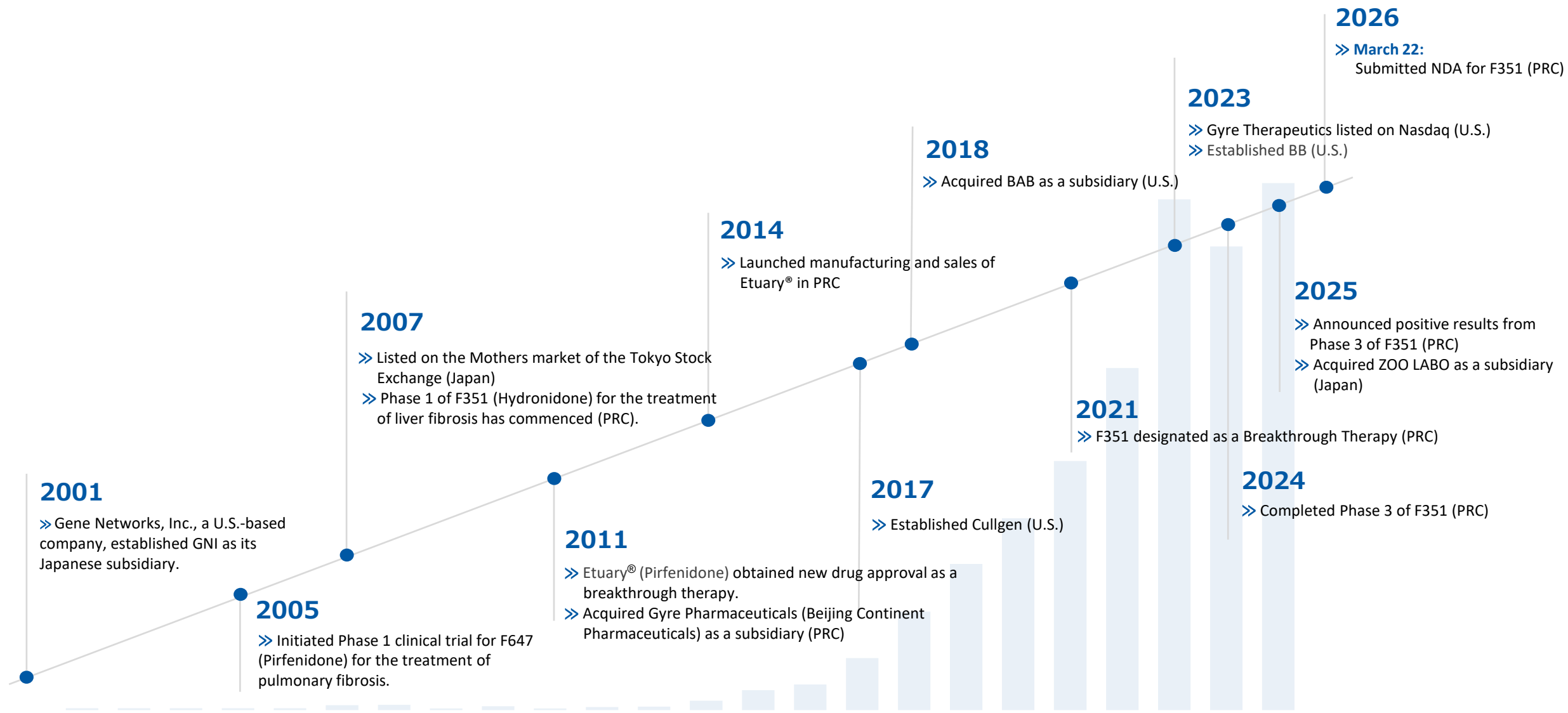
Structured R&D pipeline and marketed products : 23 (as of December 2025)

Hospitals and pharmacies in PRC : 3,000

Comprehensive sales : 400



History of GNI Group

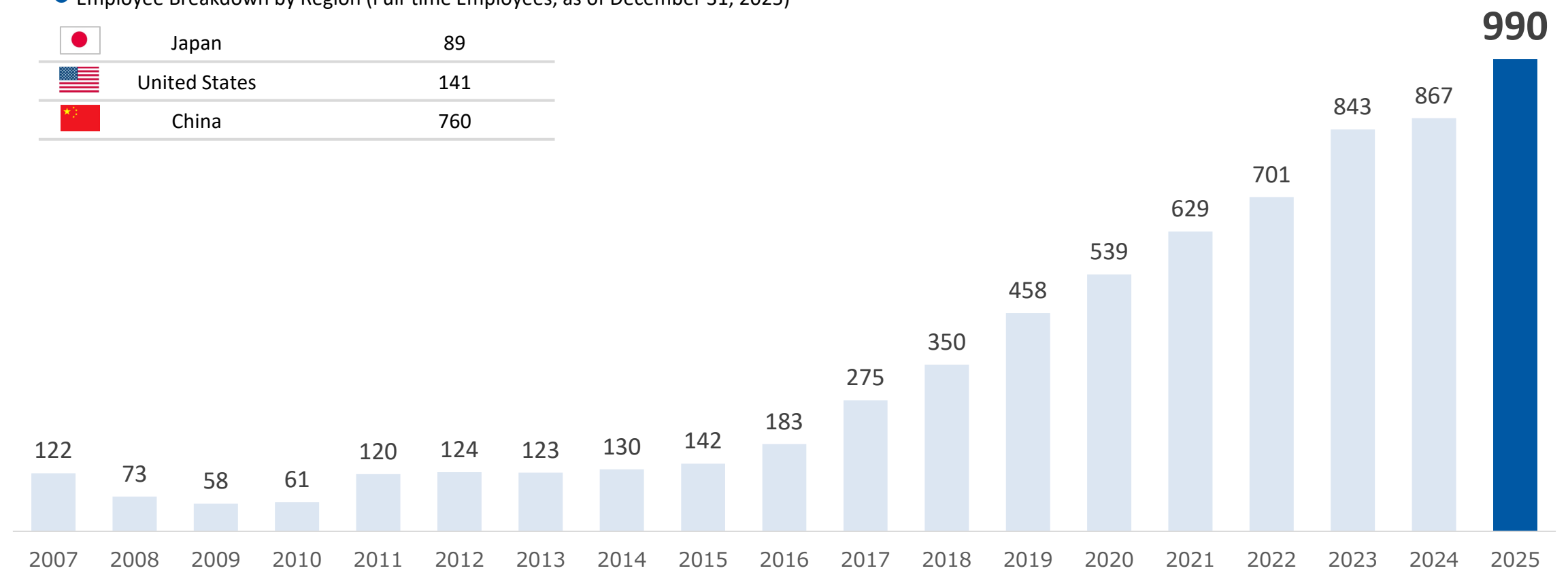


Trend in Consolidated Employees

Consolidation of ZOO LABO expanded the Group's workforce to approximately 1,000 employees.

● Employee Breakdown by Region (Full-time Employees, as of December 31, 2025)

	Japan	89
	United States	141
	China	760

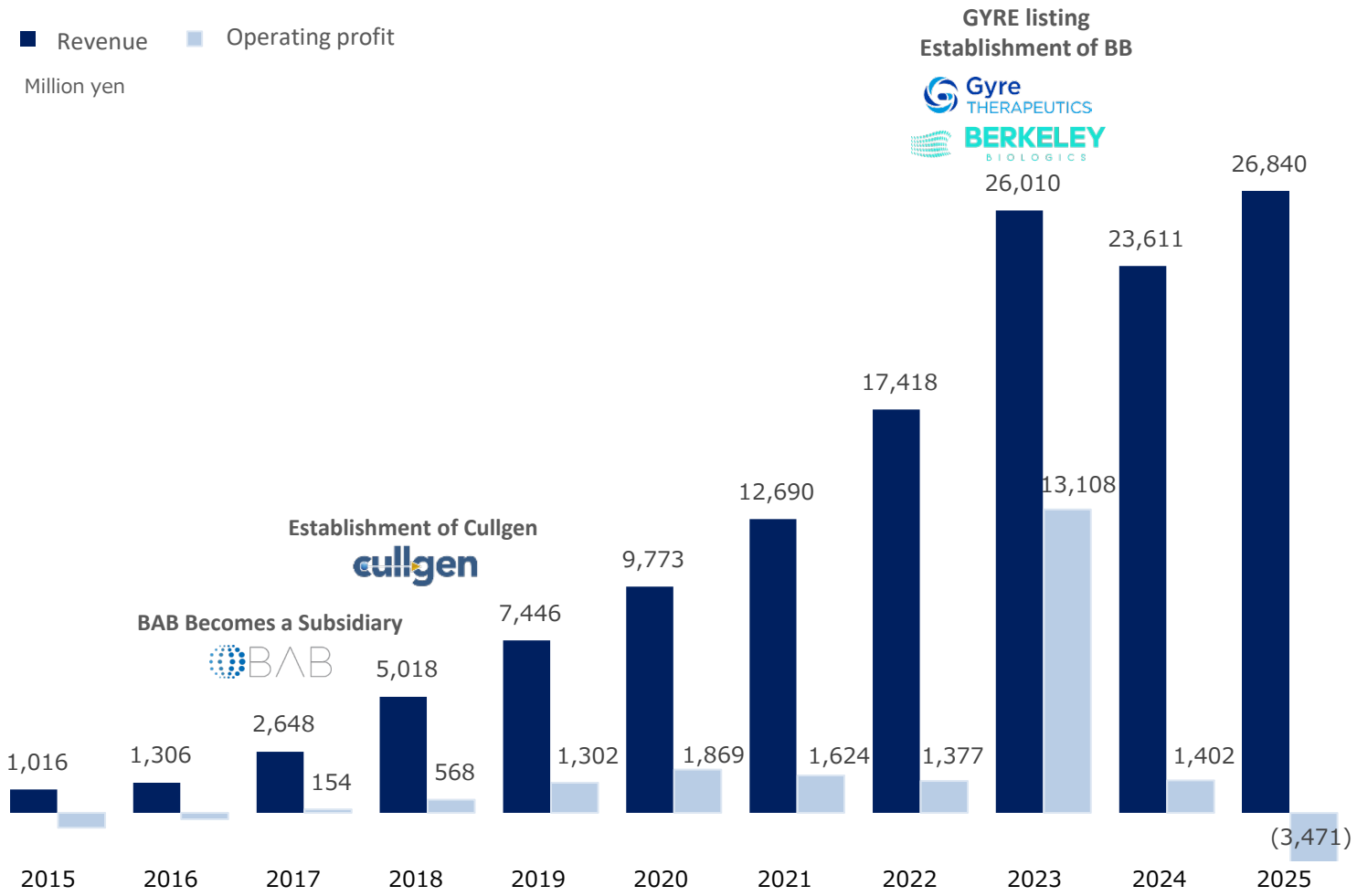


(At the time of listing)

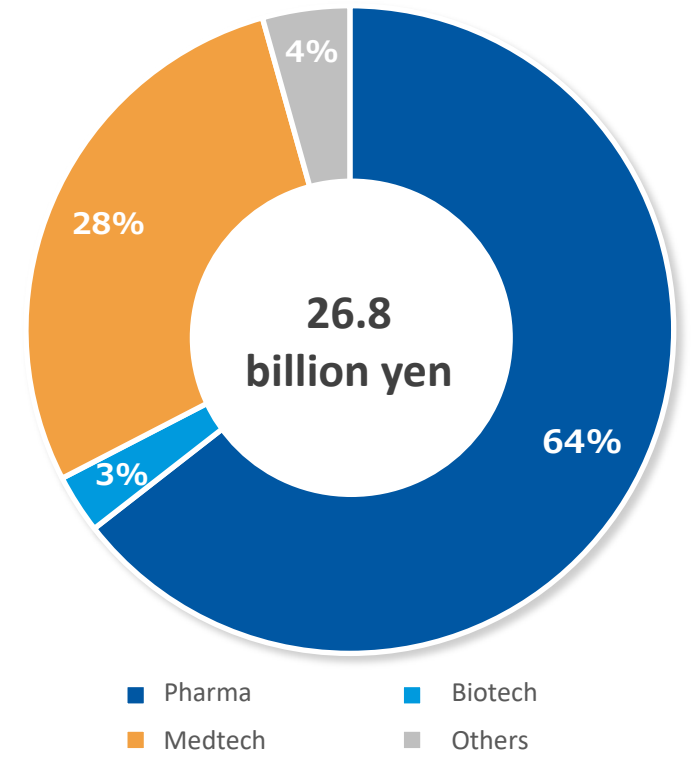
Note: The consolidated number of employees is calculated on a full-time employee basis and excludes contract, part-time, and temporary staff.

Link to Historical Performance

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

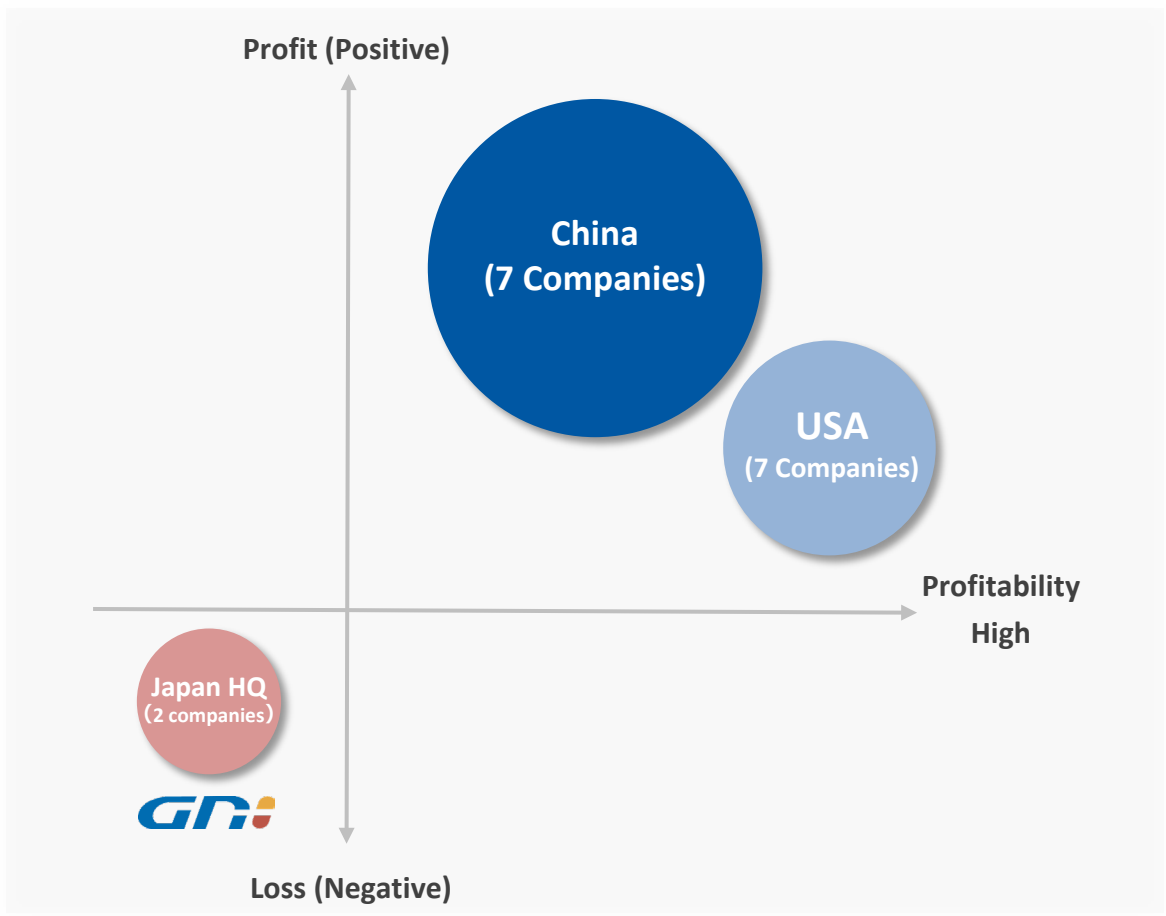


Revenue Breakdown by Segment (FY2025)



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



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



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.



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

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

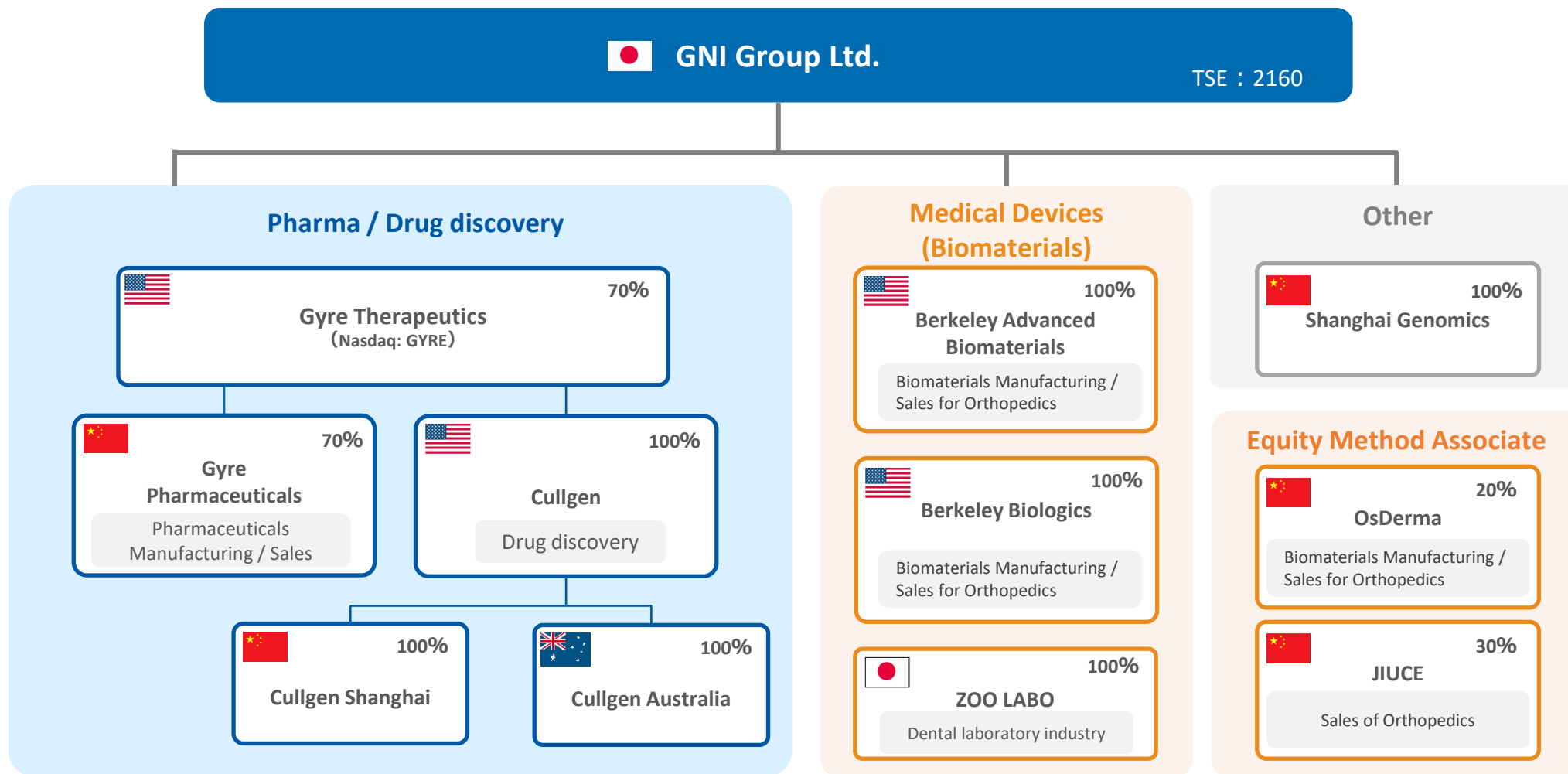
Accomplished management team in the United States with extensive international business operations experience

Post-Combination Gyre Therapeutics: At-A-Glance

Expected Date of Close Early Q2 2026









Company Name	Gyre Therapeutics, Inc. (Nasdaq: GYRE)	
Company Headquarters	San Diego, CA, with subsidiaries in Beijing and Shanghai	
Post-Merger Leadership	<ul style="list-style-type: none"> • Ying Luo – President & CEO • Yue Xiong – CSO 	<ul style="list-style-type: none"> • Ping Zhang – Chairman • Thomas Eastling – CFO
Therapeutic Assets	10 announced therapeutic programs: 1 Marketed 3 Phase 1 1 pre-NDA 3 IND-enabling studies 2 Phase 2 + line extensions	
Therapeutic Areas Addressed	<ul style="list-style-type: none"> • Inflammation / Pain • Cancer 	
WW Employees	~740 Total: ~170 R&D ~85 Manufacturing ~370 Sales & Marketing ~115 G&A	

Main Group Structure (Planned)



*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. These percentages reflect the ownership ratios after the completion of the transaction related to the acquisition of Cullgen as a wholly owned subsidiary by Gyre Therapeutics (intra-group subsidiary reorganization), announced on March 3, 2026.

Robust Portfolio: Addressing Inflammatory Diseases, Pain and Cancer

Discovery / Lead Optimization	IND Enabling	Phase 1a	Phase 1b/2	NDA	Marketed
DAC  Blood Cancers	CG923308  Solid Cancers	CG009301  Leukemia and MYC+ cancers	CG001419  Acute and Chronic Pain (IND filed)	Hydronidone (F351) CHB-associated Liver Fibrosis	ETUARY® (Pirfenidone) Idiopathic Pulmonary Fibrosis (IPF)
DAC  Solid Cancers	CG620953  Inflammatory Diseases	CG001419  Solid Tumors	F573 Acute Liver Failure (ALF)		
Protein Degradar  Fibrotic diseases	F528 Chronic Obstructive Pulmonary Disease (COPD)	F230 Pulmonary Arterial Hypertension (PAH)			

Key:

Inflammation / Fibrosis / Pain

Cancer



Degradar



DAC

Table above does not include line extensions for ETUARY and F351. The pipeline is subject to change by Gyre Therapeutics and Cullgen.

Consolidated Financial Results for FY2025

Pharma

Financial Results

Millions of yen	FY2024(Quarterly)				FY2025(Quarterly)				FY2021 Actual	FY2022 Actual	FY2023 Actual	FY2024 Actual	FY2025 Actual	Inc. / (Dec.)
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4						
Revenue	3,982	3,862	3,778	4,226	3,315	3,856	4,488	5,655	9,868	13,346	15,742	15,847	17,314	9.3%
Operating profit	1,501	898	1,095	509	810	813	1,501	90	2,501	3,735	4,054	4,003	3,213	(19.7)%
Operating profit margin	37.7%	23.3%	29.0%	12.0%	24.4%	21.1%	33.4%	1.6%	25.3%	28.0%	25.8%	25.3%	18.6%	

Financial Summary

Etuary[®] delivered record-high december sales, driving record quarterly and cumulative revenue

Revenue

- Cumulative revenue reached JPY 17,314 million (up 9% YoY), while fourth-quarter revenue totaled JPY 5,655 million (up 34% YoY).
- For the full year, revenue growth was driven by strong sales of Etuary[®], Gyre’s core product, together with contributions from two new products launched during the fiscal year.
- For the fourth quarter, revenue increased driven by the implementation of sales strategies centered on the core product Etuary[®].

Profit

- In the fourth quarter, share-based compensation expense (performance-based stock options) of JPY 951 million was recognized (non-cash expense). These stock options are granted to all employees of Gyre Pharmaceuticals and are based on shares of Gyre Therapeutics, with vesting contingent upon the progress of the F351 project and the achievement of performance targets for the period from 2025 to 2026.

Outlook for 2026

- The current fiscal year is positioned as a transition period, with priority given to regulatory affairs activities, including preparations for the NDA submission of F351*.

*Source: 0001193125-26-102700 | 8-K | Gyre Therapeutics, Inc

Biotech

Financial Results

Millions of yen	FY2024(Quarterly)				FY2025(Quarterly)				FY2021 Actual	FY2022 Actual	FY2023 Actual	FY2024 Actual	FY2025 Actual	Inc. / (Dec.)
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4						
Revenue	401	353	332	353	353	127	273	36	0	0	5,805	1,439	789	(45.2)%
Operating profit	(744)	(743)	(702)	(1,182)	(1,138)	(1,136)	(1,169)	(515)	(1,920)	(2,794)	2,374	(3,371)	(3,958)	—

Financial Summary

- Operating loss was primarily attributable to an increase in R&D expenses (JPY 2,298 million) due to the steady progress of clinical trials conducted in Australia, as well as listing preparation expenses (JPY 677 million).
- Cullgen is expected to gain indirect access to the U.S. capital markets by becoming a wholly owned subsidiary of Gyre Therapeutics.
- Following the integration, Gyre Therapeutics will fully capture (100%) the future value of Cullgen, which possesses cutting-edge technologies ([as disclosed on March 3, 2026](#)).

Gyre's Acquisition of Cullgen



Post-Integration Structure (After Transaction Closing):	Transformation into a fully integrated biopharmaceutical company with capabilities spanning drug discovery, manufacturing, and commercialization, with operational bases in the U.S. and China.									
Transaction Consideration:	USD 300 million (all-stock exchange transaction)									
Closing:	Expected in early Q2 2026									
Changes in Equity Ownership after Integration*:	<table border="0"> <tr> <td>(Before Integration)</td> <td></td> <td>(After Integration)</td> </tr> <tr> <td>Gyre Therapeutics: GNI Group ~80%</td> <td>→</td> <td>Gyre Therapeutics: GNI Group ~70%</td> </tr> <tr> <td>Cullgen: GNI Group 40%</td> <td>→</td> <td>Cullgen: 100% owned by Gyre Therapeutics</td> </tr> </table>	(Before Integration)		(After Integration)	Gyre Therapeutics: GNI Group ~80%	→	Gyre Therapeutics: GNI Group ~70%	Cullgen: GNI Group 40%	→	Cullgen: 100% owned by Gyre Therapeutics
(Before Integration)		(After Integration)								
Gyre Therapeutics: GNI Group ~80%	→	Gyre Therapeutics: GNI Group ~70%								
Cullgen: GNI Group 40%	→	Cullgen: 100% owned by Gyre Therapeutics								

* 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.

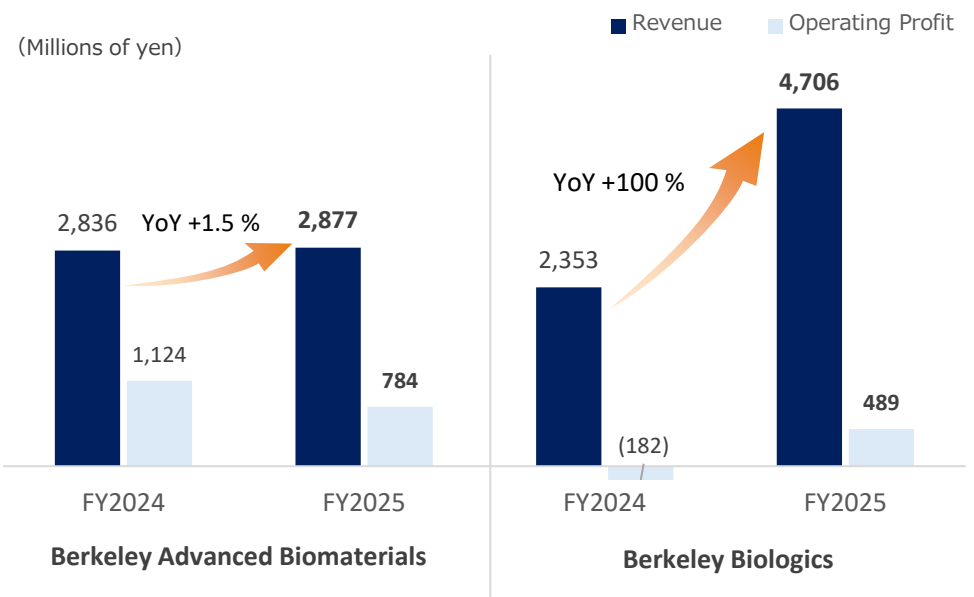
Medtech

Financial Results

Millions of yen	FY2024(Quarterly)				FY2025(Quarterly)				FY2021 Actual	FY2022 Actual	FY2023 Actual	FY2024 Actual	FY2025 Actual	Inc. / (Dec.)
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4						
Revenue	1,290	1,220	961	1,719	1,370	2,621	2,083	1,509	1,795	2,428	2,841	5,189	7,584	46.2%
Operating profit	283	424	152	84	245	528	666	(165)	844	1,110	1,133	942	1,274	35.3%

Financial Summary

Revenue and operating profit achieved the full-year budget, marking record-high growth in both revenue and profit.



- Driven by increased orders from existing customers in the fourth quarter, full-year revenue showed a stable increase compared with the previous fiscal year.
- Operating profit decreased year on year due to continued upfront investments aimed at building a transition framework from conventional OEM manufacturing to the expansion of the Company’s own private-brand (PB) strategic products.
- Approval from the U.S. Food and Drug Administration is still pending due to the impact of last year’s government shutdown.



- Although revenue decreased quarter on quarter as additional orders from newly acquired major customers secured during the current fiscal year largely ran their course, sales approximately doubled year on year. As a result, operating profit returned to profitability.
- With the launch of a new business in the field of regenerative medicine (organ transplantation), BB has already acquired new customers, and further growth is expected in the next fiscal year.

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	FY2024	FY2025	Inc. / (Dec.)	Factors for increase/decrease
Revenue	1,156	1,169	13	
Operating profit/ Loss	8,819	(4,089)	(12,908)	
GNI Group	5,511	(1,441)	(6,952)	<ul style="list-style-type: none"> Recognition in 2024 of JPY 6,021 million in reversal of allowance for doubtful accounts following repayment of loans related to Gyre shares held by GNI USA (non-cash), resulting in a decline in profit in the current year. Loss of JPY 630 million from a share price forward transaction in 2025 (one-time).
GNI USA	5,100	(70)	(5,170)	<ul style="list-style-type: none"> Decrease in profit due to recognition in 2024 of JPY 6,518 million in gain on transfer of Gyre shares related to repayment of loans from the Company.
Gyre Therapeutics	(1,062)	(1,677)	(615)	<ul style="list-style-type: none"> Stock-based compensation expense of JPY 793 million recognized in 2025 (non-cash).
Micren	(20)	(297)	(277)	<ul style="list-style-type: none"> Impairment loss of JPY 280 million recognized in 2025 (non-cash).
Shanghai Reef	(476)	(248)	228	
Other 9 companies	(234)	(356)	(122)	<ul style="list-style-type: none"> Impairment loss of JPY 228 million recognized in 2025 related to Shanghai Genomics Technology (non-cash).

Note: Calculated based on IFRS.

Consolidated Income Statement

The pharma and medtech businesses performed strongly, achieving record-high revenue with JPY 3.0 billion YoY increase.

Millions of yen	FY2024	FY2025	Inc. / (Dec.)	Factors for increase/decrease
Revenue	23,611	record-high 26,840	3,229	• Existing pharmaceutical and medtech businesses achieved record-high sales, driving overall revenue growth.
Gross profit	18,037	19,993	1,956	
SG&A	15,771	18,989	3,218	
R&D	2,811	3,298	487	• R&D expenses increased due to progress in Cullgen's development activities.
Operating profit	1,402	(3,471)	(4,873)	• YoY decrease due to the absence of prior-year one-off loan repayment gains (approx. JPY 1.6billion). • Cullgen listing-related expenses (approx. JPY 0.67billion). • Loss from share price forward transactions in Q1 (approx. JPY 0.63billion). • Impairment losses on goodwill and intangible assets (approx. JPY 0.53billion).
Income before income taxes	238	(4,634)	(4,872)	
Net profit	(9)	(7,150)	(7,141)	
Profit attributable to owners of the parent	1,098	(4,244)	(5,342)	

Segment

Millions of yen	Pharma		Biotech		Medtech		Others	
	FY2024	FY 2025	FY2024	FY 2025	FY2024	FY 2025	FY2024	FY 2025
Revenue	15,847	record-high 17,314	1,439	789	5,189	record-high 7,584	1,156	1,169
Operating profit	4,003	3,213	(3,371)	(3,958)	942	1,274	8,819	(4,089)

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

Millions of yen	FY2023 Q4	FY2024 Q4	FY2025 Q4	Inc. / (Dec.)	
Total non-current Assets	33,475	42,720	43,057	337	
Goodwill	14,246	15,994	16,648	653	
Intangible assets	8,852	11,026	12,347	1,321	• Capitalization of R&D expenses incurred by Gyre Pharmaceuticals in China after the initiation of Phase 3 clinical trials (refer to the next page).
Total Current Assets	30,793	29,222	40,734	11,512	
Trade accounts receivable	3,973	6,236	8,056	1,820	• Increase of JPY 1.9 billion in Gyre Pharmaceuticals
Inventories	2,217	2,529	3,752	1,223	• Increase of JPY 0.6 billion in Gyre Pharmaceuticals
Cash and cash equivalents	21,633	10,115	21,101	10,986	• Approximately JPY 12.6 billion raised through a public offering in July 2025. • Acquisition of ZOO LABO in December 2025.
Total Liabilities	27,764	32,229	31,948	(280)	
Total non-current Liabilities	19,571	19,764	22,354	2,590	• Increase in unpaid interest on Cullgen's preferred shares (recognized as a financial liability for accounting purposes until the completion of the acquisition transaction with Gyre Therapeutics).
Total current Liabilities	8,193	12,464	9,594	(2,870)	• Decrease in short-term borrowings of JPY 3.3 billion.
Total Equity	36,504	39,713	51,842	12,129	
Capital and Other Components of Equity	20,434	19,887	35,434	15,547	
Retained earnings	8,790	9,888	5,644	(4,244)	
Other Components of Equity	4,569	6,669	9,240	2,571	
Equity attributable to owners of the parent company to total assets	33,794	36,446	50,320	13,874	
Non-controlling Interests	2,710	3,267	1,522	(1,746)	

Consolidated Balance Sheet / Goodwill and Intangible Assets

Under IFRS, impairment tests for goodwill and intangible assets are conducted annually.

If future cash flows cannot be reasonably estimated, they are subject to impairment.

Breakdown		JPY Amounts (millions of yen)				Foreign Currency (Local Currency Basis)			
		FY2023 Q4	FY2024 Q4	FY2025 Q4	Inc. / (Dec.)	FY2023 Q4	FY2024 Q4	FY2025 Q4	Unit
		14,246	15,995	16,648	653				
Goodwill	Gyre Pharmaceuticals	173	188	194	6	8.7	8.7	8.7	Million RMB
	Gyre Therapeutics	7,080	7,616	7,535	(81)	48.1	48.1	48.1	Million USD
	Berkeley Advanced Biomaterials	6,701	6,653	6,584	(69)	42.1	42.1	42.1	Million USD
	Berkeley Biologics	1,175	1,230	1,217	(13)	7.8	7.8	7.8	Million USD
	Micren ①	271	271	0	(271)	271	271	0	Million JPY
	ZOO LABO	—	—	1,081	—	—	—	1,081	Million JPY
	GNI Hong Kong	31	35	34	(1)	0.2	0.2	0.2	Million USD
		8,852	11,026	12,347	1,321				
Intangible assets	Patent rights ②	0	202	0	(202)	0	9.3	0	Million RMB
	Customer relationships	2,362	2,468	2,290	(178)	16.7	15.6	14.6	Million USD
	Brand (PPA) ③	67	69	63	(6)	0.5	0.4	0.4	Million USD
	Capitalized development costs	6,383	8,038	9,214	1,176				
	Gyre Therapeutics ④	4,254	4,745	4,697	(49)	30.0	30.0	30.0	Million USD
	Gyre Pharmaceuticals ⑤	2,128	3,293	4,518	1,224	106.8	152.0	202.0	Million RMB

- ① Micren As a result of the impairment test conducted by an independent third-party during the current period, goodwill of JPY 270 million was impaired.
- ② Patent rights As a result of the impairment test conducted for the current period, intangible assets related to technologies held by Shanghai Genomics Technology amounting to JPY 200 million were impaired.
- ③ Customer relationships Customer turnover over time at the acquired entity is recognized as amortization expense.
- 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	FY2024 Q4	FY2025 Q4	Note
Cash Flow from Operating Activities	(3,164)	(2,408)	<ul style="list-style-type: none"> Although the pre-tax loss of JPY 4.6 billion had a significant impact, the deficit in cash flow narrowed due to factors such as a reduction in corporate tax expenses.
Cash Flow from Investment Activities	(10,361)	(536)	<ul style="list-style-type: none"> Reversal of the approximately JPY 4.0 billion purchase of securities and approximately JPY 1.7 billion purchase of investment securities conducted in the previous fiscal year for the purpose of surplus fund management. Recovery of a JPY 1.5 billion deposit following the termination of the share price forward transaction. Includes cash outflow related to the acquisition of shares of ZOO LABO.
Cash Flow from Financial Activities	694	13,738	<ul style="list-style-type: none"> Raised JPY12.6 billion through the public offering in July 2025.
Net effect of exchange rates changes	1,313	193	
Net (decrease)/ Increase in cash and cash equivalents	(11,517)	10,986	
Cash and cash equivalent at beginning of year	21,633	10,115	
Cash and cash equivalents at end of year	10,115	21,101	

R&D expense

- Increase in R&D expenses mainly due to progress in Phase 1 clinical trials conducted in Australia by Cullgen (up JPY 466 million YoY).
- The capitalization of F351's Phase 3 clinical trial

Millions of yen	FY2022 Actual	FY2023 Actual	FY2024 Actual	FY2025 Actual	Inc. / (Dec.)
Consolidated R&D expenses	2,545	2,557	2,811	3,298	487
Capitalized development costs	606	940	1,165	1,176	11
Total	3,151	3,497	3,976	4,474	497

Background for Not Disclosing the FY2026 Earnings Forecast

Regarding the consolidated earnings forecast for FY2026, key factors expected to have a material impact on performance include the timing of approval and launch of F351 (a therapeutic candidate for liver fibrosis associated with chronic hepatitis B) currently under NDA by Gyre Therapeutics, the anticipated drug price, the scale and timing of upfront investments, as well as the progress of Cullgen's R&D and the timing of its potential listing.

At this stage, it is difficult to reasonably estimate these factors. Accordingly, the earnings forecast is currently undisclosed and will be presented as "TBD" until a reliable estimation becomes possible.

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): RMB 631 million (+16.6% YoY) (approx. JPY 14.6 billion) H1 FY2025: RMB 371 million (+37.4% YoY) (approx. JPY 8.6 billion)	31.50%	Estimated RMB 1.6–2.1 billion (JPY 33.6–44.1 billion)	A core product of Shanghai Huanghai Pharmaceutical (a subsidiary of Baiyang Pharmaceuticals), with annual sales of approximately RMB 500 million (approx. JPY 10.5 billion). 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.	○	RMB 6,000–8,000 (approx. JPY 120,000–160,000)	Cordyceps sinensis mycelium (fungal biomass)
Biejia Ruangan Tablets (Biejia Ruangan)	Inner Mongolia Furui Medical	FY2024: approx. RMB 300 million (approx. JPY 7.0 billion) H1 FY2025: approx. RMB 150 million (+1.6% YoY)	15%	Estimated RMB 0.8–1.0 billion (JPY 17.0–21.0 billion)	One of the two dominant products alongside Fuzheng Huayu. It was the first drug approved in China for the treatment of liver fibrosis in 1999 and, as a pioneer, has achieved very high nationwide recognition and extensive prescription history. In China’s hospital market for anti-liver fibrosis traditional Chinese medicines, it holds an estimated market share of 25–30%. GNI estimates its market size at RMB 0.8–1.0 billion (approximately JPY 16–21 billion).	○	RMB 12,000–14,000 (approx. JPY 250,000–290,000)	Turtle shell (Biejia)
Anluo Huaxian Pills (Anluo Huaxian)	Senlong Pharmaceutical	Approx. RMB 100 million (approx. JPY 2.3 billion)	5%	Estimated RMB 0.2–0.3 billion (JPY 4.2–6.3 billion)	A key product following the top two. It is included in clinical guidelines and maintains a stable market presence, with an estimated market share of several percent to around 10%.	○	RMB 4,000–5,000 (approx. JPY 80,000–100,000)	
Top 3 Products	Top 3 companies	RMB 1.03 billion (JPY 23.8 billion)	51%	RMB 2.6–3.4 billion (JPY 54.8–71.4 billion)				
Total Market	Entire market	RMB 2.02 billion (JPY 46.7 billion)	100%	RMB 5.1–6.7 billion (JPY 107.5–140.0 billion)				

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 realistically estimated that approximately **400,000 to 600,000 patients** are effectively treated annually across China with three major traditional Chinese medicines (TCM). Assuming that the top three products account for an estimated 50% market share, the total number of patients in the Chinese market is estimated to be approximately **800,000 to 1,200,000**.

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	RMB 1.2–1.6 billion <i>Note: FY2024. Sales in the first half of 2025 increased by 37% YOY.</i>	Approximately RMB 1.0–1.1 billion (primarily through hospital channels)	Approximately RMB 0.5–0.6 billion
Annual treatment cost	Approximately RMB 8,000–10,000 (approx. JPY 160,000–200,000)	According to reports, the standard cost for one course of treatment (3 months) is approximately RMB 1,500–2,000. The cost for a full year of treatment is approximately RMB 6,000–8,000. The figure of “JPY 250,000–290,000” 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 RMB 20 per day.	Approximately RMB 5,000–7,000
Estimated number of patients	Approximately 150,000–250,000	Approximately 150,000–200,000	Approximately 80,000–120,000

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.

F351 is expected to drive demand and establish a new market

In current antifibrotic treatment, traditional Chinese medicines are primarily prescribed by physicians who are receptive to integrative medicine approaches. However, prescriptions are often withheld by physicians trained in Western medicine who place strong emphasis on rigorous evidence, citing insufficient clinical data.

In contrast, our investigational drug F351 has generated robust evidence demonstrating improvement in liver fibrosis in a rigorous placebo-controlled Phase 3 clinical trial.

Based on this evidence, we expect increased adoption among physicians who have previously been reluctant to prescribe traditional Chinese medicines, leading to further expansion of the market. Furthermore, following its launch, GNI believes that F351 has a high likelihood of being recommended as a first-line antifibrotic therapy in guidelines issued by liver disease societies in China.

If realized, F351 is expected to become established as a standard of care across medical institutions throughout China, benefiting a large number of patients while also serving as a key driver of the Group's revenue growth.

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	Approximately JPY 410,000	Approximately JPY 320,000
Annual cost at the time (RMB)	RMB 13,200	RMB 18,000	RMB 14,160
Pharmaceutical company	U.S.	U.S.	U.S.

Antiviral agents such as entecavir (ETV) suppress viral replication, whereas F351 is a therapeutic candidate designed to directly improve established liver fibrosis. Currently, no drugs have been approved anywhere in the world with proven efficacy in this area.

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TPD and DAC Platform Technology to Revolutionize Drug Discovery

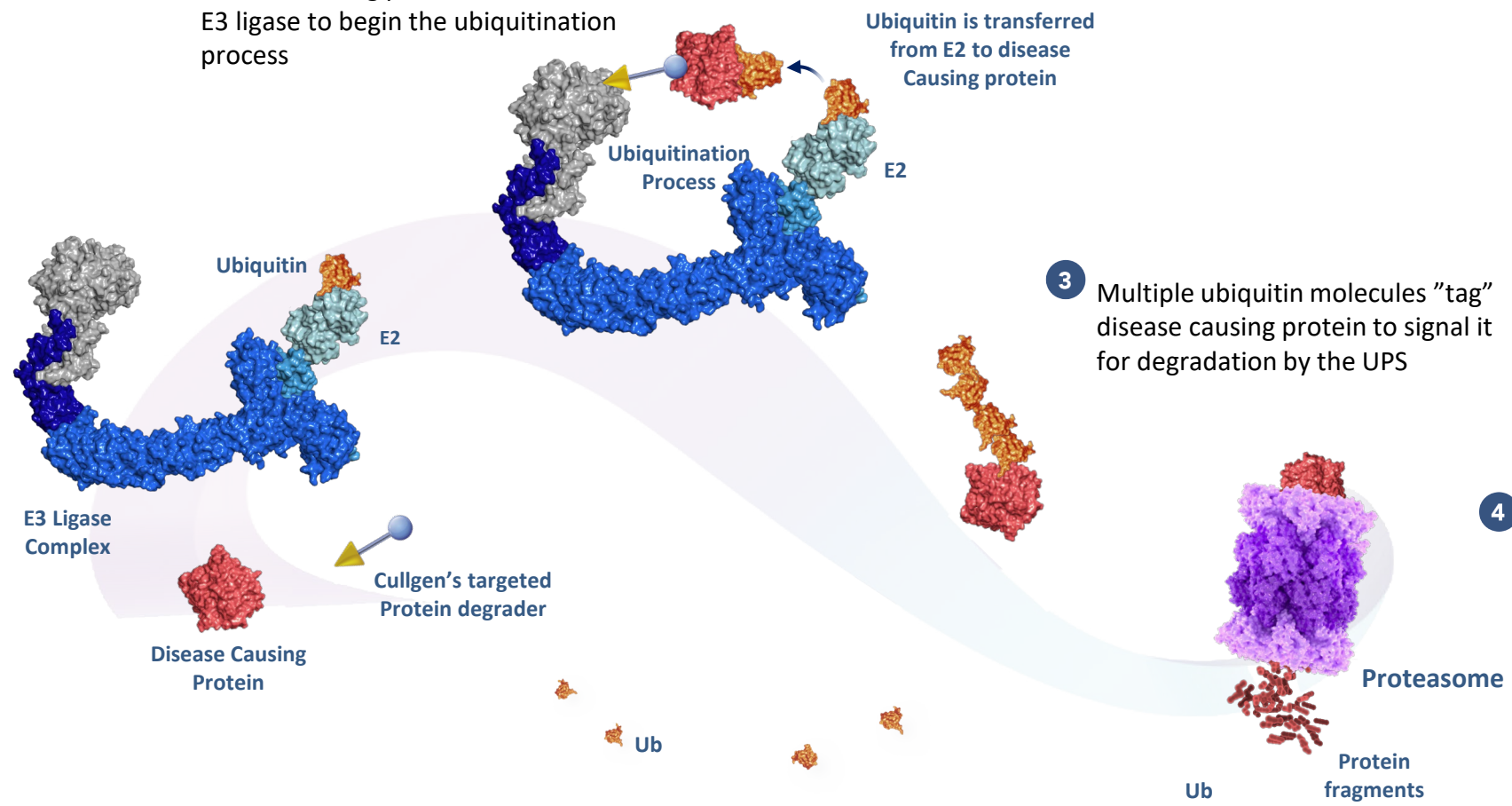
Hijacking the Ubiquitin Proteasome System to Target Undruggable Disease-causing Proteins

1 Targeted protein degraders are bi-functional molecules that bind to disease causing proteins and specific E3 ligases inside cells

2 Targeted protein degrader binds to disease causing protein and recruits E3 ligase to begin the ubiquitination process

3 Multiple ubiquitin molecules "tag" disease causing protein to signal it for degradation by the UPS

4



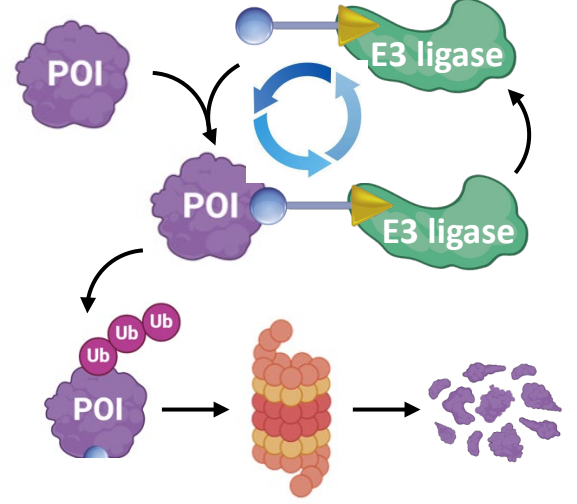
Degrader-Antibody Conjugates (DACs) Combine the Advantages of ADCs and TPD and Represent the Next-Generation of ADCs

ADC
(Antibody drug conjugate)

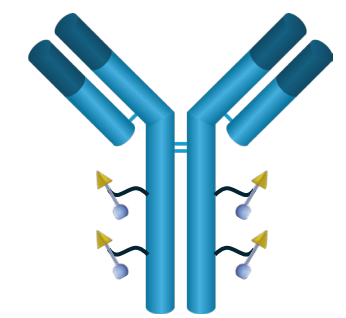


+

TPD
(Targeted protein degradation)



DAC
(Degrader antibody conjugate)



HIGH POTENCY

The catalytic mechanism of action of TPDs ensures small quantity of degrader delivered by the antibody to achieve sufficient efficacy.

IMPROVED PK

Extended half-life, reduced systemic clearance, improved solubility, and bypassing the need for oral bio-availability or cell permeability optimization.

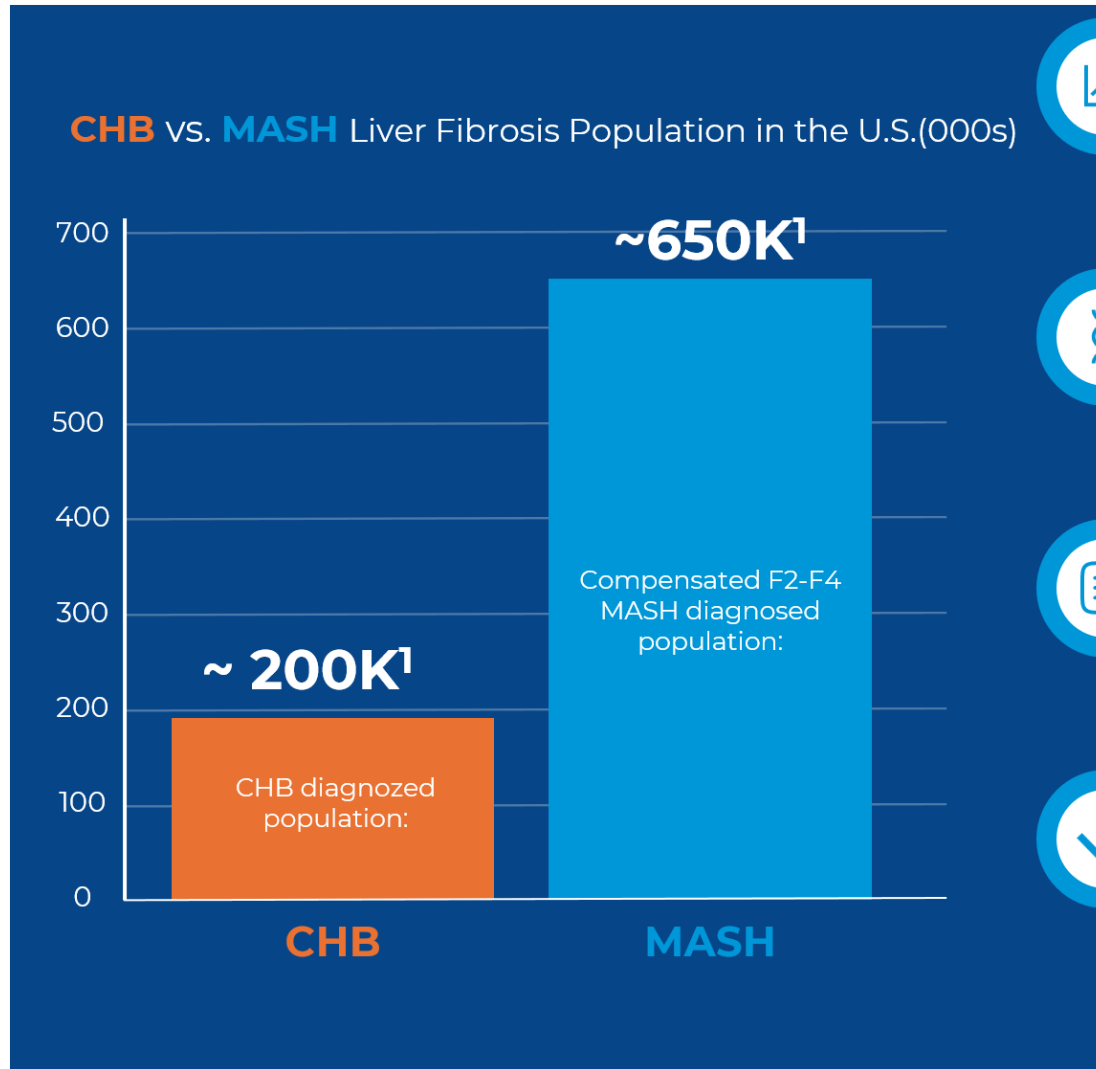
IMPROVED SAFETY

Reduced toxicity through dual target selectivity at the cell surface (antibody-tumor associated antigen) and intracellularly (degrader-target protein).

Leading Inflammation/Fibrosis Therapeutic Programs

Expanding F351's Global Market Potential Tyk2 for Rheumatoid Diseases

Exploring F351's Potential in CHB-related and/or MASH-related Compensated Liver Fibrosis and Cirrhosis in the U.S.



Market Opportunity

In the U.S., the MASH fibrosis market is approximately **7.2 times larger** than the CHB fibrosis market.

Clinical Rationale

Hydronidone modulates **TGF-β / p38γ / Smad7** signaling pathway — directly targeting fibrosis progression and **offering a differentiated approach from metabolic agents.**

Regulatory Pathway

Hydronidone's CHB data **helps to reduce risks in MASH development** and potentially supports *accelerated regulatory review and fast track.*

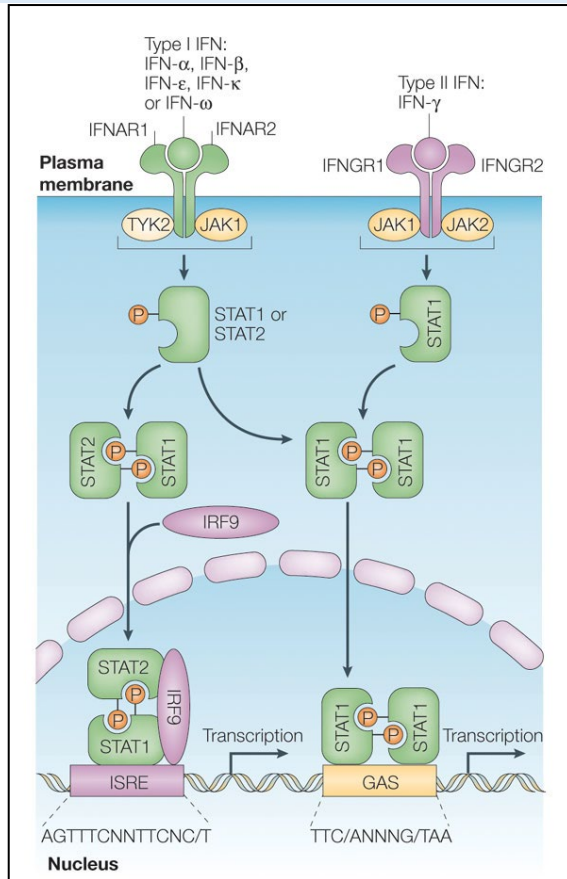
Competitive Differentiation

Hydronidone's unique anti-fibrotic approach positions it as a **complementary therapy** — not a competitor — to metabolic agents like THR-β, GLP-1s, and FGF21.

1. Based on analysis of third-party epidemiological research, published academic studies, and internal modeling.

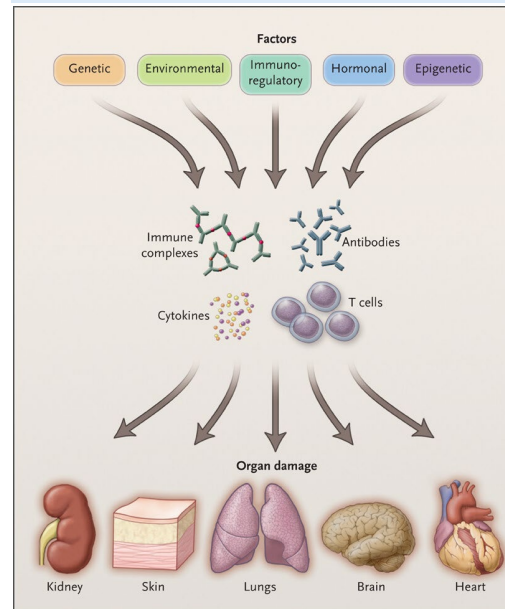
Dual Targeting of TYK2 and JAK1 for Autoimmune Diseases, Focus on Systemic Lupus Erythematosus and Rheumatoid Arthritis

A. TYK2/JAK - STAT signaling



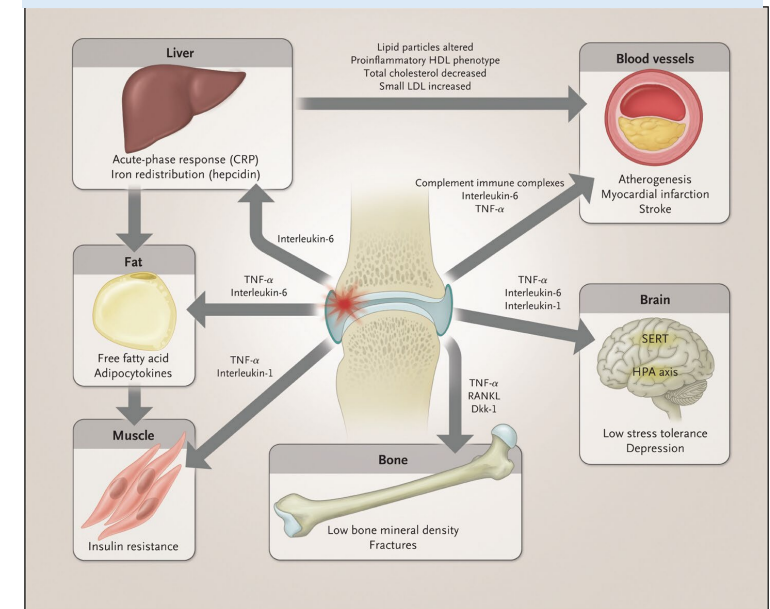
Platanias, LC. (2005) *Nat Rev Immunol* PMID:15864272

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

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>

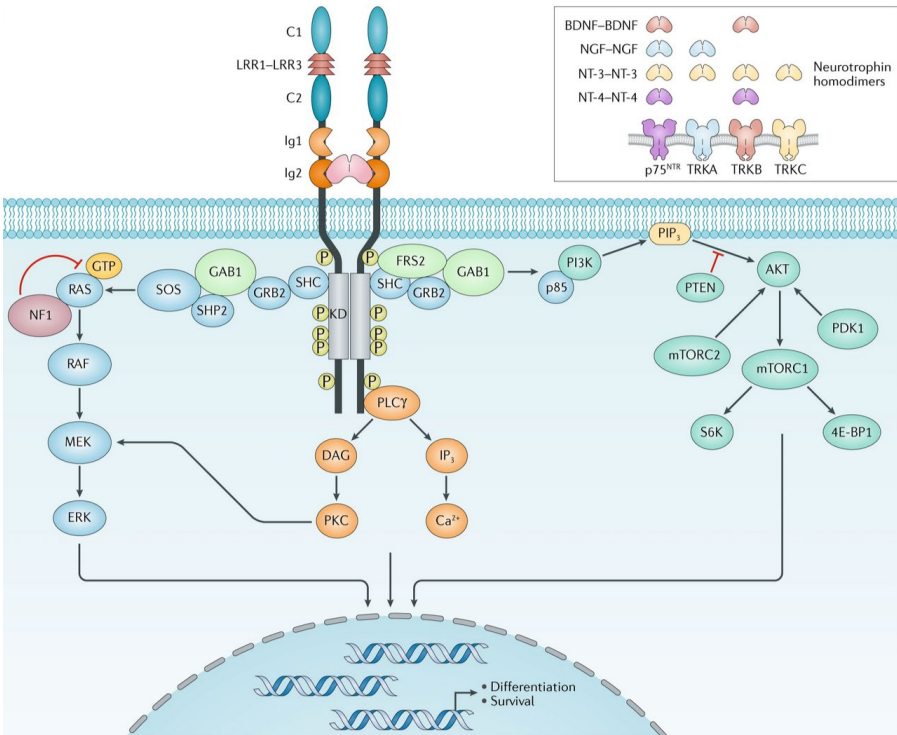
Cancer Programs

CG001419: for pan-TRK Cancers
CG009301: GSPT1 Degradar for AML and MYC+ Cancers

Tropomyosin Receptor Kinases (TRKs) Are Receptors for Neurotrophins Including NGF

A. TRK signaling pathways

GNI's interpretation: The signaling pathway through which TRK, after receiving stimulation, transmits signals intracellularly to promote cell proliferation and survival.

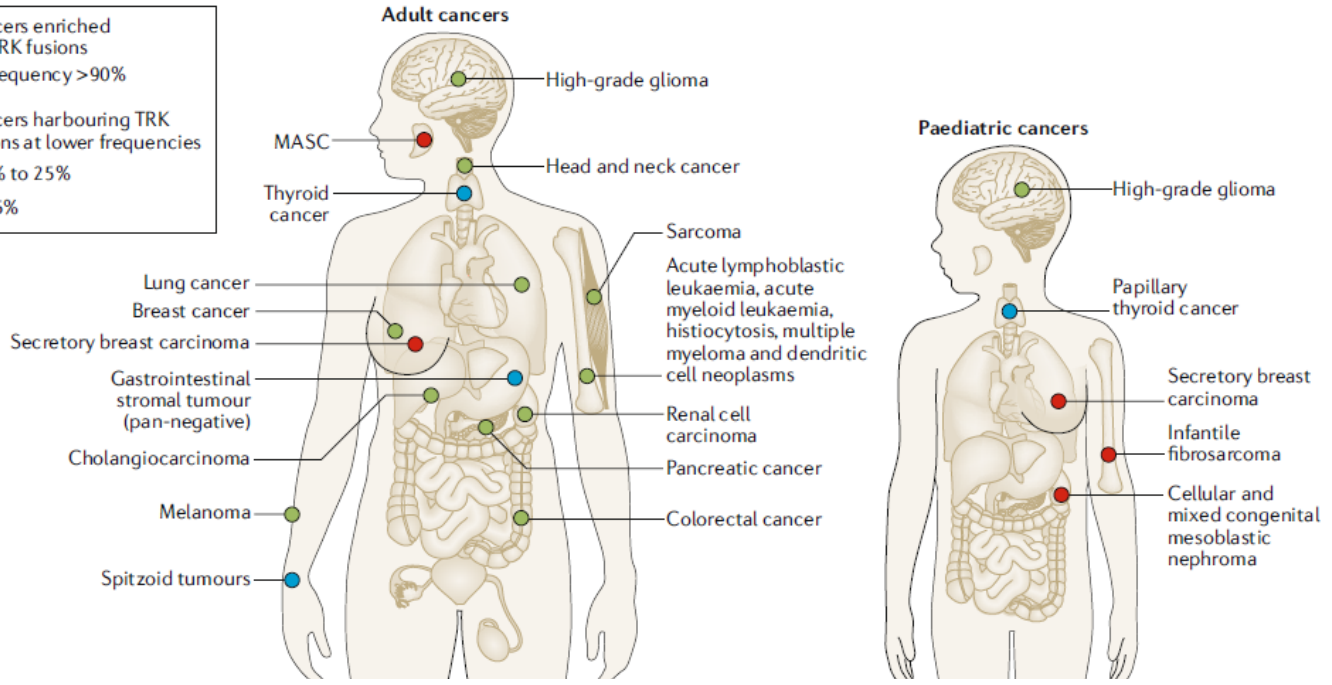


B. Activation of TRK in multiple solid tumors

GNI's note: Oncogenic mutations lead to aberrant activation of neuronal TRK, which promotes cancer cell survival and metastasis.

Cancers enriched for TRK fusions

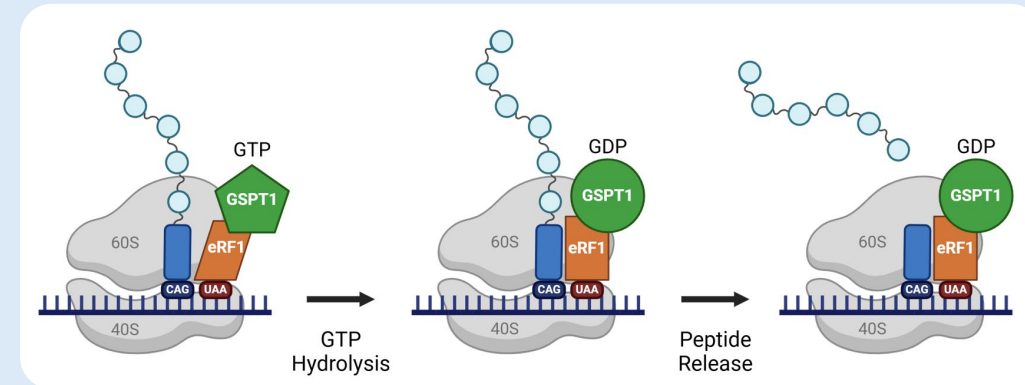
- Frequency >90%
- 5% to 25%
- <5%



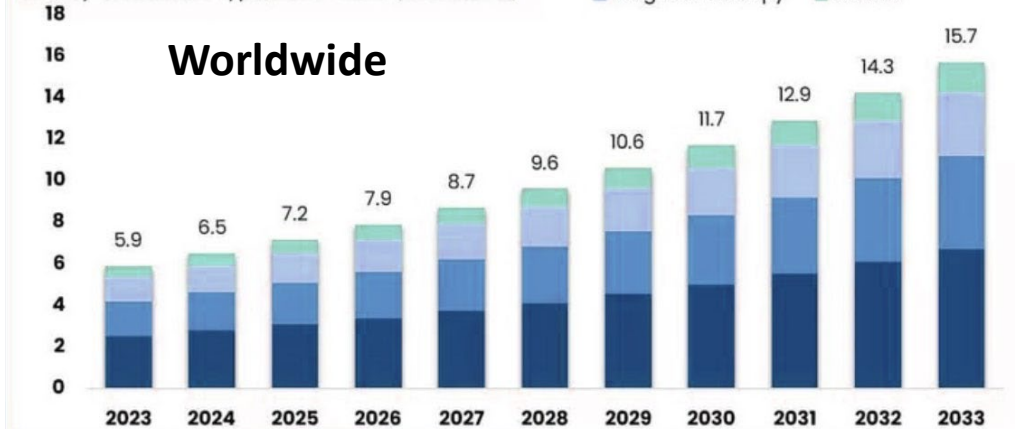
Cocco, Scaltriti & Drilon (2018) *Nat Rev Clin Oncol* PMID: 30333516

CG009301 Targeting GSPT1 for AML and MYC+ Cancers

- » GSPT1 controls protein translation termination and plays important function for leukemia stem cells and tumor cells with MYC overproduction.
- » GSPT1 lacks an active site and is often considered “undruggable”.
- » Cullgen has developed a potent and selective GSPT1 degrader, CG009301.
- » Preclinical studies have validated the selectivity, potency and safety of CG009301.



Blood Cancer Treatment Market
Size, by Treatment Type, 2023-2033 (USD Billion)



The Market will Grow At the CAGR of: **10.3%** The Forecasted Market Size for 2033 in US\$: **15.7 B**

US Patient Population

AML ¹	MDS ¹	ALL ¹	MYC-amplified solid tumors ^{2,3}
~20,800 new cases	~10,000 new cases	~6,500 new cases	28%
11,220 mortality	30-40% MDS progress to AML ⁴	1,330 mortality	

¹ 2024 by American Cancer Society estimates
² The Cancer Genome Atlas (TCGA) estimates
³ Schaub et al (2018) *Cell Syst* PMID: 29596783
⁴ Volpe et al (2022) *Clin Lymphoma Myelom Leuk*, PMID: 34544674

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