



GNI Group Ltd.

FY2024 Full Year Financial Results Corporate Presentation



**We Bring New
Hope to Life.**

Agenda

1. Company Overview

2. Financial Highlights

3. FY2024 Topics

4. Financial forecast for FY2025

5. FY2025 Topics

6. GNI Group's Value Proposition

7. Supplementary Materials

1. Company Overview

Company Overview

■ Head Office

3rd Floor, Nihonbashi Honcho YS Building,
2-2-2, Nihonbashi-Honcho
Chuo-ku, Tokyo 103-0023

■ Incorporation

November 2001

■ Paid Capital

13,277 million yen (as of December 31,
2024)

■ Listing

TSE Growth Market
Listed in August 2007
Securities code: 2160

■ Main Business

Global pharmaceutical R&D,
manufacturing and distribution,
and biomaterials business

■ Director, Representative Executive Officer, President, and CEO

Ying Luo Ph.D.

■ Number of Employees (group-wide)

867 (as of December 31, 2024)

■ Operating Countries

Japan, USA, the People's Republic of China,
and Australia



**Director, Representative Executive Officer,
President, and CEO**

Ying Luo Ph.D.

- As a Chinese-American, he pioneered the new profitable business model that leverages the unique strengths of the pharmaceutical industry in the PRC, the U.S., and Japan in developing new therapeutic products for unmet medical needs.
- He obtained a Ph.D. in Molecular Biology/Biomedical Sciences from the University of Connecticut Health Center in 1991. He has co-authored over 35 research studies and publications and is an inventor on over 16 patents during his 30+ years of biotech career.
- He was selected as one of the “Forbes China 100 most influential Chinese 2024”.

Business model	Pharmatech	Biotech	Medtech (Biomaterials)
Name	 Gyre Therapeutics, Inc. Gyre Pharmaceuticals	 Cullgen Inc.	 Berkeley Advanced Biomedicals LLC (BAB) Berkeley Biologics LLC (BB)
Topics	<ul style="list-style-type: none"> Listed on NASDAQ Development of anti-fibrotic and anti-inflammation drugs Manufacturing and commercialization (ETUARY® and others) 	<ul style="list-style-type: none"> Listing announcement (November 14) Drug discovery platform (TPD) in cancers and others Research Collaboration (Astellas Pharma) Received investment from AstraZeneca 	<ul style="list-style-type: none"> Conducted an M&A in 2023
FY2023 Revenue/ Operating profit	BC: 15.74 billion yen 3.99 billion yen	5.8 billion yen 2.69 billion yen	2.74 billion yen 1.33 billion yen
Q4 FY2024 Cumulative sales	15.85 billion yen	1.44 Billion yen <small>*Received 4.72 billion yen as an upfront payment from Astellas Pharma → Next milestone (additional)</small>	5.17 billion yen
Future	<ul style="list-style-type: none"> F351 clinical trial results Nintedanib and Avatrombopagmaleate to be launched 	<ul style="list-style-type: none"> Listing Approx. 1.5 billion yen in stable profit Clinical trial for pain in Australia Aiming for the next milestone 	<ul style="list-style-type: none"> Prepare for future listing New CEO from J&J joined

Major Pharmaceutical & Drug Discovery

<Pharmaceutical>

ETUARY® (Generic name : Pirfenidone)



- Chinese : 艾思瑞、English : ETUARY®
- Treatment for idiopathic pulmonary fibrosis (IPF) and **market leader** in the PRC
- Clinical developments are underway for expansion of indications (Three Phase 3 trials)
- Donating to NPO for patients in the PRC every year

<Drug Discovery>

F351 (Generic name : Hydronidone)



- Lead product candidate targeting liver fibrosis, a disease that cannot be cured by existing therapeutic agents
(Phase 3 clinical trial completed on October 22)
- Potential blockbuster drug
- Recognized as a '**Breakthrough Therapy**' by the China National Medical Products Administration in 2021
- Indicated for Hepatitis B and MASH* in the PRC and MASH* in the U.S.

Targeted Protein Degradation



- Utilizing its proprietary uSMITE™, technology platform for targeted protein degradation
- Aiming to develop novel drugs targeting cancer, pain, and autoimmune diseases
- Received investment and appointed a director and a scientific advisor from AstraZeneca
- Signed a large-scale contract with Astellas Pharma
3 phase 1 ongoing (2 in the PRC and 1 in Australia)

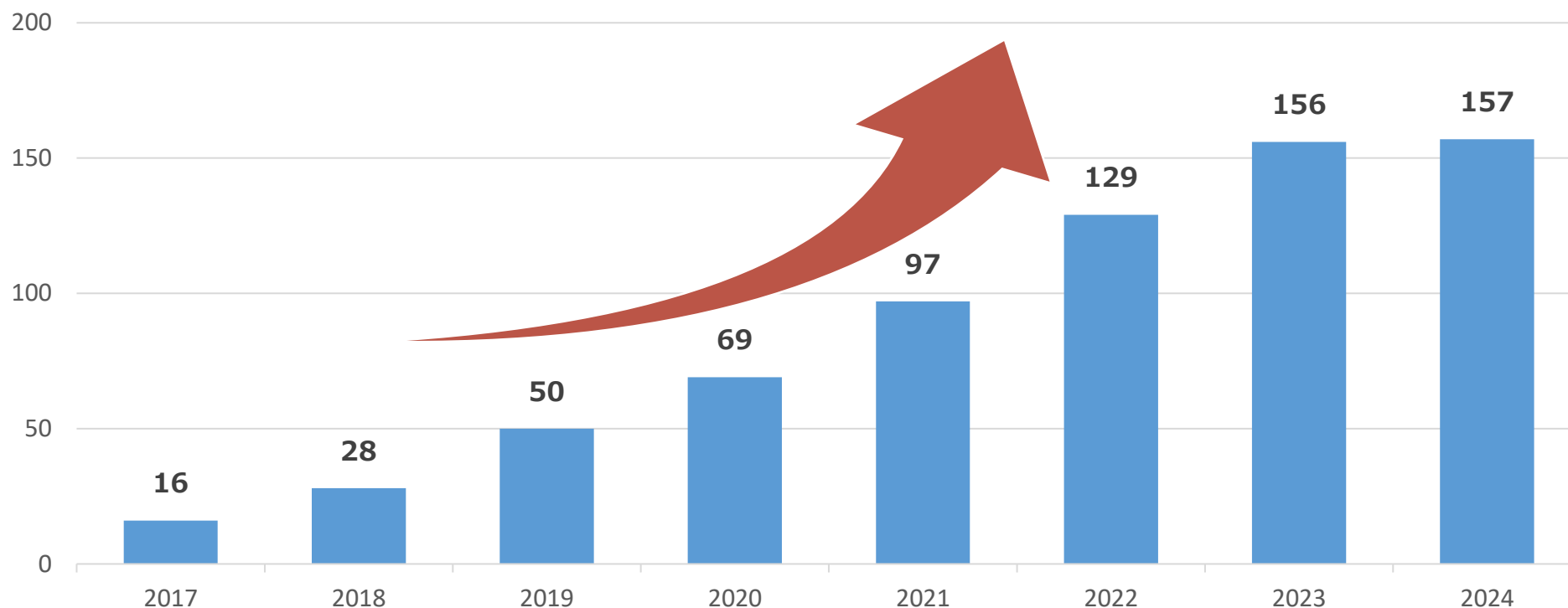
*Metabolic Dysfunction Associated Steatohepatitis

Who we are (1)

From Drug Discovery Success to Commercialization

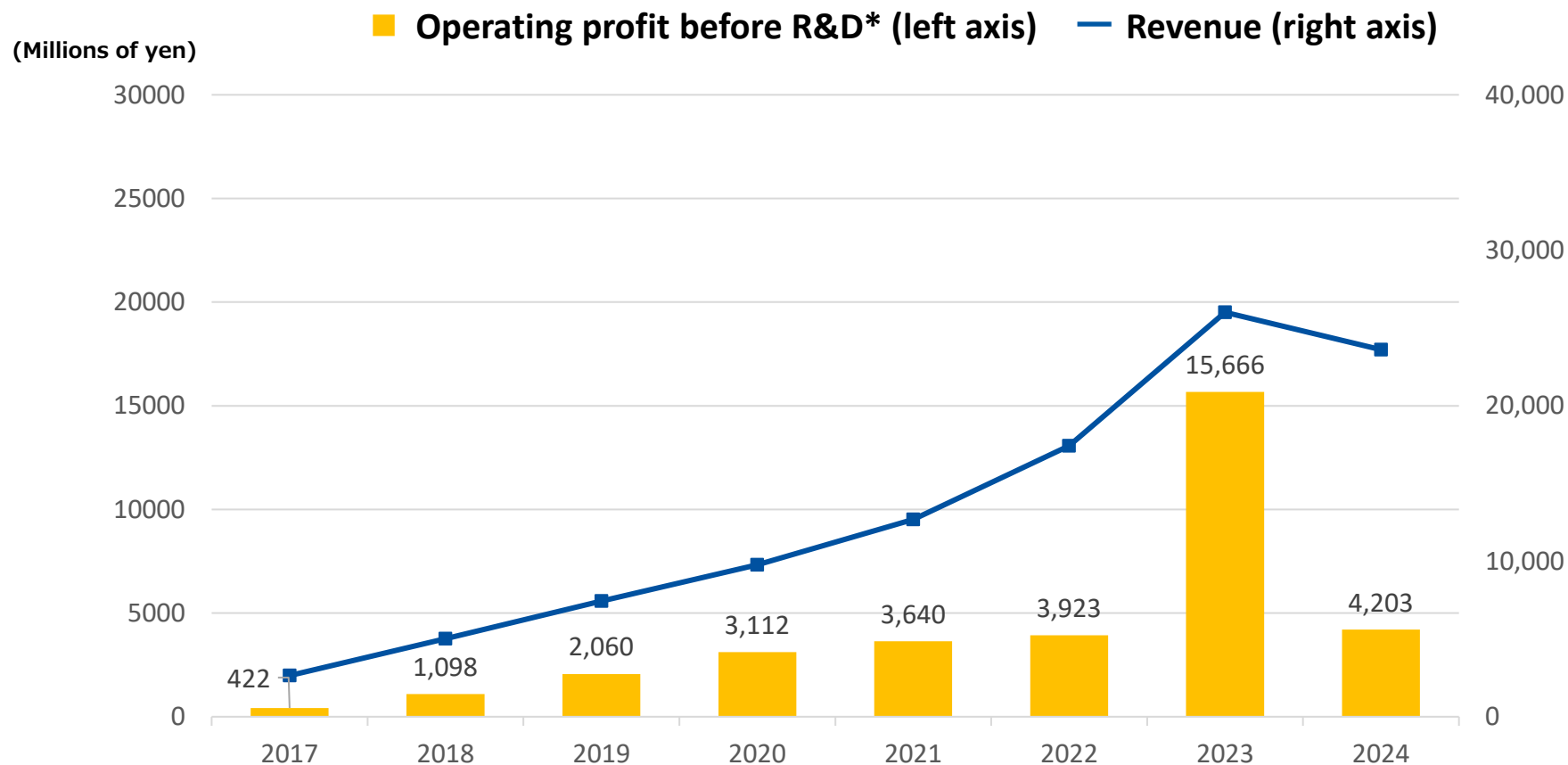
ETUARY® Sales

(100 million yen)



Who we are (2)

A Rare Drug Development Company With Commercialization Capability and Operating Profit



* Operating profit before R&D = Operating profit + R&D expenses

Who we are (3)

Globally recognized for high development capabilities

Successful development of ETUARY[®]

Completed Phase 3 trial for F351*

**Ongoing large-scale joint research
with Astellas Pharma**

**Investment let by AstraZeneca into Cullgen
with one board seat**

Who we are (4)

Listed Subsidiaries is GNI's Strategy for Value Realization and Global Expansion

1. **GYRE's successful listing on NASDAQ enables Japanese shareholders to see the value of our strong presence in China**
2. **Cullgen will be our second in pipeline to give GNI's expansion on global stage**
3. **Medtech Group listing will come up in the future**
4. **Listing of subsidiaries make values of each subsidiary visible to GNI shareholders**
5. **Listing of subsidiaries will provide support and reduce stock price volatility of GNI**

GNI Group is a group company that

- **Operates globally in the U.S. and China as well as Japan.**
- **Demonstrates world-class development capabilities while succeeding in drug discovery and making profits as a pharmaceutical manufacturer.**
- **Accelerates further new drug development and realizes huge growth potential under the vision of "We Bring New Hope to Life".**

In other words,

As a **Growth stock**, we will continue our strong curve of growth in the coming years, especially after F351 commercialization.

As a **Value stock**, we will deliver values to our shareholders through individual listing of our strong subsidiaries.

2. Financial Highlights

Forecast for 2024

Differences in financial results due to postponement of fiscal year

Millions of yen	FY2024 Forecast	FY2024 Actual	Reason
Revenue	39,556	23,611	M&A projects that were expected to be highly feasible were postponed
Gross profit	34,624	18,037	
Operating profit	16,286	1,402	Postponement of listing gain due to Cullgen listing (Assumed gain on listing at the time of the announcement was approximately 14,764 million yen)
Income before income taxes	15,552	238	
Net profit	12,287	(130)	
Profit attributable to owners of the parent	7,058	977	

Consolidated income summary

Steady growth for the Group as a whole, excluding an upfront payment 4.92 billion last year

Millions of yen	Q4 FY2023 Cumulative total	Q4 FY2023 (excluding one-time payments*)	Q4 FY2024 Cumulative total	Inc. / (Dec.)	Inc. / (Dec.) (excluding one-time payments*)
Revenue	26,010	21,087	23,611	(9.2)%	12.0%
Gross profit	22,431	17,507	18,037	(19.6)%	3.0%
SG&A	15,292		15,771	3.1%	
R&D	2,557		2,811	9.9%	
Operating profit	13,108		1,402	(89.3)%	
Income before income taxes	12,612		238	(98.1)%	
Net profit	9,504		(130)	(101.4)%	
Profit attributable to owners of the parent	8,094		977	(87.9)%	

Segment

Millions of yen	Pharmatech	Biotech	Medtech	Others	Consolidation adjustments
Revenue	15,847	1,439	5,169	1,176	(20)
Operating profit	4,003	(2,700)	896	1,449	(2,246)

*35 million USD upfront payment in 2023 for the alliance between consolidated subsidiary Cullgen and Astellas Pharma Inc.

Result of Stock Price Reservation Trading Program

Contributed to earnings with a full-year positive impact Profit and Support to GNI Shareholders

	FY2024 4Q	Full-year
Other expences (Stock valuation gain) Stock valuation gain related to stock forward contract with Macquarie	573 million yen	119 million yen

Consolidated balance sheet summary

Millions of yen	FY2021 End Actual	FY2022 End Actual	FY2023 End Actual	Q4 FY2024 Cumulative total	Inc. / (Dec.)
Total non-current assets	12,109	16,759	33,475	40,724	17.8%
Total current assets	18,187	17,147	30,793	29,222	(5.4)%
Total assets	30,296	33,906	64,269	69,947	8.1%
Total non-current liabilities	8,487	10,592	19,338	19,378	0.2%
Total current liabilities	2,543	3,503	8,426	10,895	22.7%
Total liabilities	11,030	14,096	27,764	30,273	9.0%
Capital and other	17,108	17,125	20,434	19,887	(2.6)%
Retained earnings	307	696	8,790	9,768	10.0%
Other components of equity	1,444	3,147	4,569	6,749	32.3%
Equity attributable to parent	18,860	20,969	33,794	36,405	7.2%
Non-controlling interests	405	△1,158	2,710	3,267	17.0%
Total shareholders' equity	19,266	19,810	36,504	39,673	8.0%

Sufficient cash

Shares of listed subsidiary GYRE are Cash Equivalent assets

Future addition of shares of Cullgen and Medtech Group expected

2024 Q4 **160.2 billion yen**

Cash-equivalent assets	2024 Q4
Cash and cash equivalents	14.31 billion yen
Time Deposits	2.81 billion yen
Market Value of Gyre Shareholdings*	139.28 billion yen
Non-Current Assets	
Long-term Deposits	3.83 billion yen

*Calculated by our company based on the stock price and exchange rate at the end of the period

R&D expenses

Steady progress in drug development

(Millions of yen)	FY2021 Actual	FY2022 Actual	FY2023 Actual	Q4 FY2024 Cumulative total
Consolidated R&D expenses	2,015	2,545	2,557	2,811
Capitalized development costs	336	606	940	1,165
Total	2,351	3,151	3,497	3,976*

*14% YoY increase

3. FY2024 Topics

Progress of Featured Events

Events	Progress	Details
1 . Received results of Phase 3 clinical trial of F351	Clinical trials completed	Waiting for top line data to be released.
2 . Cullgen's listing	Announced	Listing announced. to be listed in 2025.
3 . Progress in R&D and clinical trials	Announced	Two new products will contribute to sales in 2025.
4 . M&A	Unachieved	Actively considering all opportunities for synergy and value enhancement.
5 . Preparation progress for prime market transition	Ongoing	Lead managing securities firm confirmed. Awaiting listing approval for Cullgen (subsidiary restructuring) and internal organizational development.

Expansion of pharmaceutical sales lineup

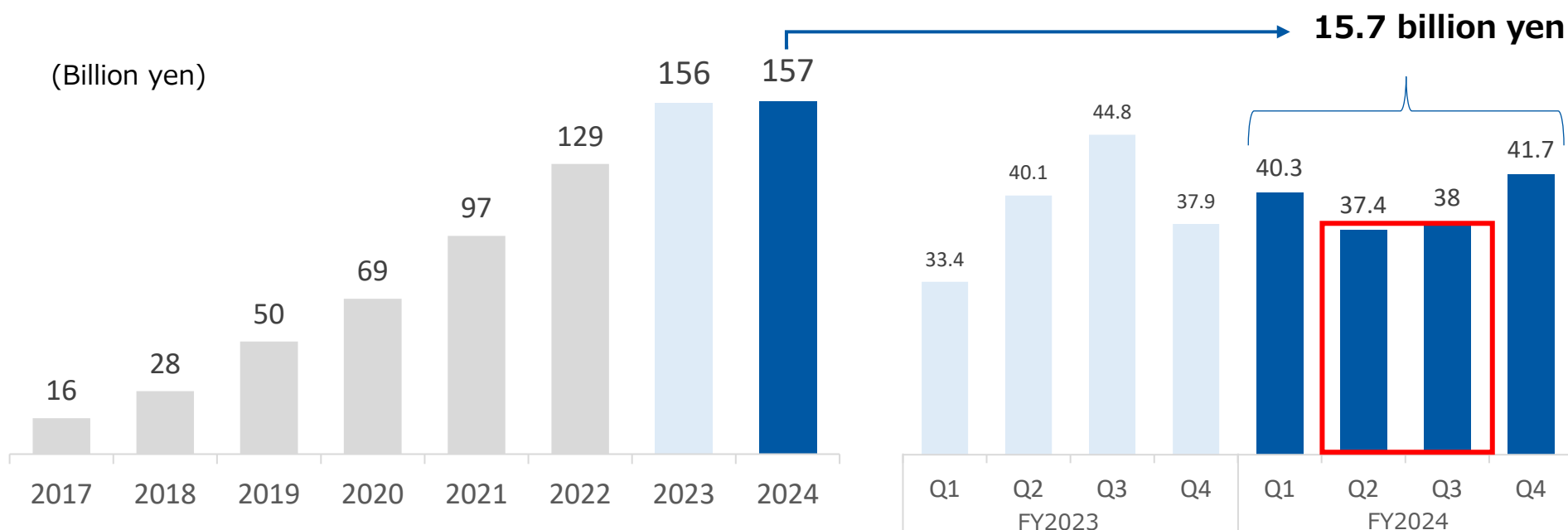
Product	Indication	Present
Nintedanib	IPF	Production and sales rights acquired (May 2024)
	systemic sclerosis-associated interstitial lung disease (SSc-ILD)	
	progressive fibrotic interstitial lung disease (PF-ILD)	
Avatrombopag Maleate	Thrombocytopenia due to chronic liver disease	Sales approval acquired (Jun 2024)
	Chronic Immune Thrombocytopenia (ITP)	Indication expansion(January 2025)

Contributed to this period's revenue

Steady sales of key products in very challenging Chinese economic environment

ETUARY® Sales

Quarterly sales



Anti-corruption campaign



Restrictions on marketing activities (Q2~Q3)



Recovery in Q4

Completion of Phase 3 clinical trial for F351

About F351

- The drug with the potential to become the first treatment for approximately 150 million liver fibrosis patients in China
=Potential blockbuster drug
- **Designated as a "breakthrough therapy" by the NMPA**
- Considering global expansion with MASH in 2025.

Events	Date
Completion of Phase 3 clinical trials	October 2024
Topline data disclosure	Awaiting the release of the analysis results
NDA application	2 to 3 months after data release if smooth
NDA approval	6 to 8 months after NDA if smooth

New Blockbuster Pipeline Starts with Pain as Indication

① IND application approval – October 2024

- CG009301 (GSPT1 protein-targeting decomposition drug)
 - Indication: Malignant blood tumors(leukemia)
 - Third IND application approval following TRK

② Phase 1 clinical trial – from January 2025

- CG001419
 - Indication: Acute and chronic pain
 - Clinical trial initiated in Australia

Non-opioid, Non-NSAID pain killer for multi billion dollar market

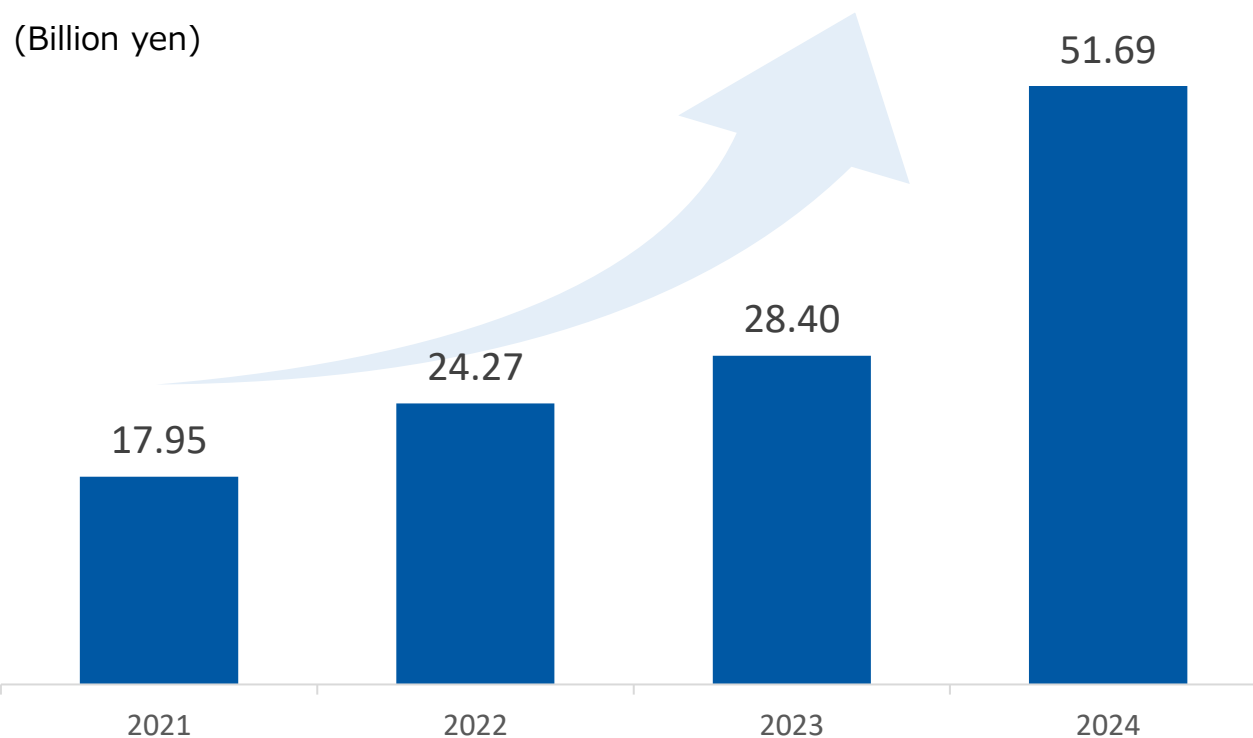
Cullgen's listing announcement

Rapid listing through merger
with PULMATRiX, Inc. a **NASDAQ listed company**

The second listing of GNI subsidiaries following GYRE

Increase in awareness and credibility
+ Promotion of future new drug development

Target sales of 5 billion yen achieved



M&A Effects

Partnership with JAIC

Holding 18.7% of JAIC's shares

1. Attract capital from global investors including China, the US and Europe to Japanese companies
2. Support the expansion of products held by invested companies into the Chinese market
3. Explore the possibility of forming group companies through co-investment/M&A

*Of the 18.7%, 17.95% is held in proportion to the investment amount of the ASIA Fund, while our direct holding is 0.78% (as of the end of January)

Selected for JPX-Nikkei Mid and Small Cap Index

- Effective from August 30
- **1.86% → 2.11%*** of the portfolio
- GNI Group has a high free-float market capitalization and holds the second highest weighting among the 200 stocks



Goals for this FY and beyond: JPX-Nikkei Index 400 Index

*Compared to the previous quarter as of December 31, 2024

[Reference] Performance Comparison of Our Stock and Index

Index / Stock Price	Annual Change Rate (2023-2024)
TOPIX	17.9%
TSE Growth Market	(8.6)%
GNI Group (2160)	20.3%

TSE Growth Market

- The longest consecutive decline in history for four years
- TSE Growth Market was sold off amid rising interest rates in Japan

GNI Group

- Ongoing IR activities
- Coverage initiated by Mizuho Securities

4. Financial Forecasts for FY2025

Financial Forecasts for FY2025

Consolidated Financial Results

Does not include Cullgen's milestone revenues and M&A revenues

Millions of yen	FY2024 Actual	FY2025 Forecast	Inc./ (Dec.)
Revenue	23,611	28,733	21.7%
Gross profit	18,037	22,954	27.3%
Operating profit	1,391	23,217	1569.1%
Income before income taxes	238	22,541	9371.0%
Net profit	-130	15,868	12,307.7%
Profit attributable to owners of the parent	977	12,058	1134.2%

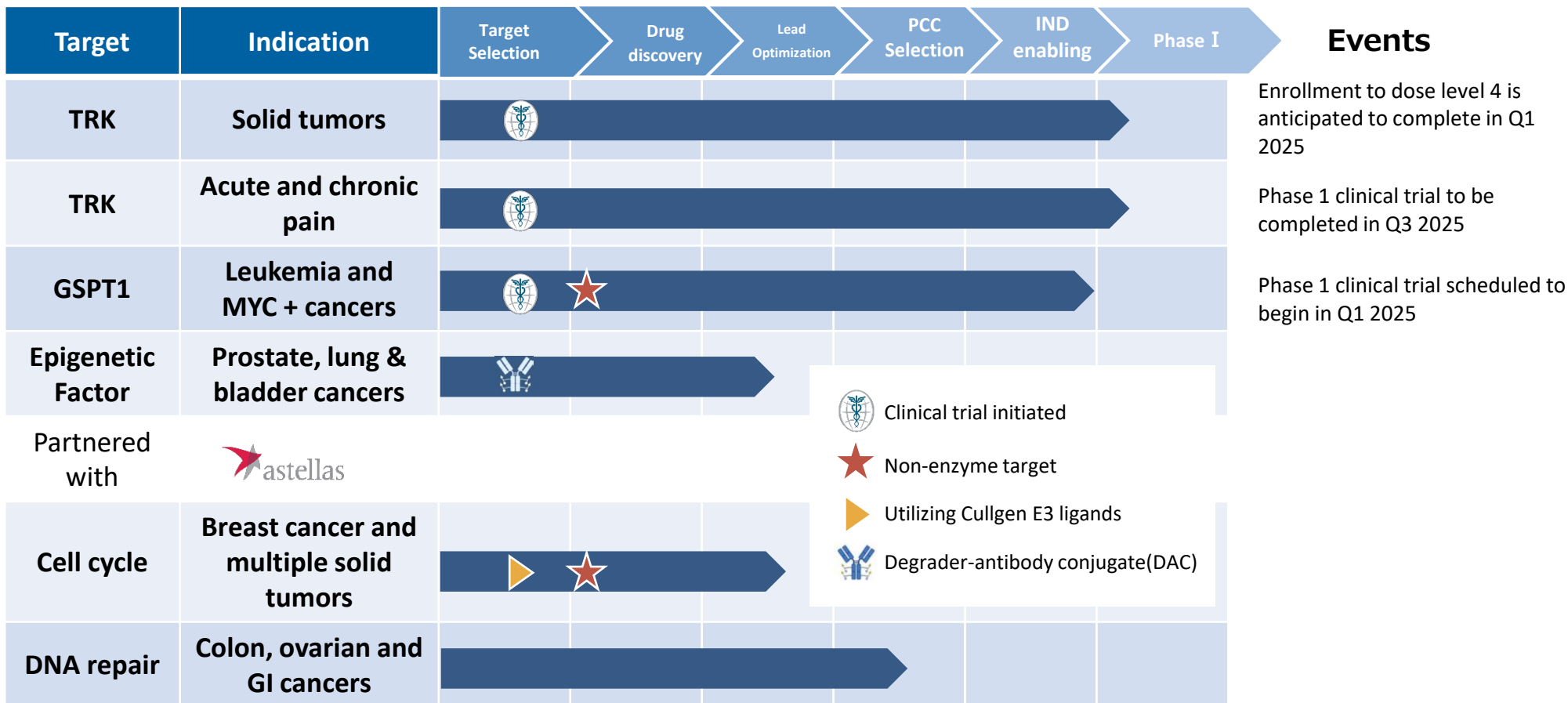
Segment

Millions of yen	Pharmatech	Biotech	Medtech	Others	Consolidation adjustment
Revenue	20,202	955	6,159	1,525	(108)
Operating profit	4,640	3,982	1,269	16,314	(1,703)

*The results of Gyre Therapeutics, Inc. are included in Others.
Biotech segment reflects results through Q2 2025.

5. FY2025 Topics

Seek new licensing alliances for the future



*Schedule is based on current assumptions and is subject to change.

Cullgen's listing

Pending approval by CSRC

*It was listed one week after the CSRC application was accepted when GYRE was listed

Listing promptly after approval



Assumed gain on GNI ownership on listing (operating profit)

At the time of announcement (November 13, 2024): **14.8 billion yen**

At present (February 4, 2025) : **42 billion yen**

*Other income, less legal fees and other expenses, is expected to be recorded as operating income. Since the date of Cullgen's listing is the date on which revenues are generated, actual revenues will fluctuate depending on the initial price at the time of IPO and exchange rates.

Further expansion of Medtech business

1. Expansion of sales lineup through new product launches
2. New sales in China and US



Aiming for sales scale of 10 billion yen in 3 years

To establish domestic business

Accelerate business growth including investment and M&A



Obtaining cash flow
Establish a management base that is not dependent on group companies

6. GNI Group's Value Proposition

Stable revenue base

**Sales products and sales systems that lead to
reliable sales**

+

Development capabilities to support future growth

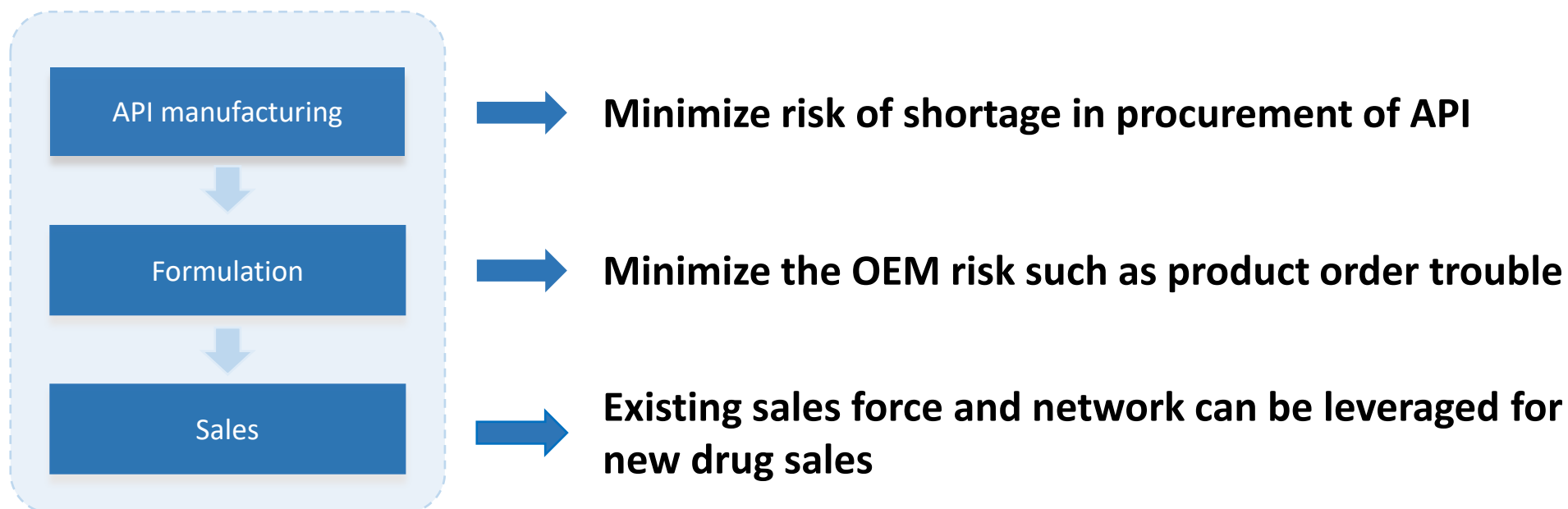
**R&D technologies and systems that lead to
future profits**



**Become a global mid-sized pharmaceutical company capable
of high profitability and growth**

Highly profitable vertical integration model

- Developed a unique model by integrating all stages from API production to sales within the group
- **The average gross margin over the past five years : 95.3%**



Stable production and sales amid global drug shortages

GNI Group's Value Proposition



Market capitalization **167.8 billion yen**

≠Resolution of valuation gap

Pharma/Biotech	Biotech	Medtech
Listed on NASDAQ in 2023	Announced listing on NASDAQ in 2024	Prepare for the future listing
Market capitalization of GNI 132.4 billion yen	Market capitalization of GNI Soon to be manifested	Market capitalization of GNI ???
Book value: 13 billion yen	Book value: 7.3 billion yen	Book value: 8.5 billion yen
*Madrigal Pharmaceuticals Inc. market cap: 1,185.3 billion yen	*Arvinas, Inc. market cap: 187.8 billion yen	*2024: Net sales 5.2 billion yen, operating income 0.9 billion yen 2023: Net sales 2.7 billion yen, operating income 1.33 billion yen

7. Supplementary Materials

Reinforcement of future revenue base

Product	Indication	Progress	Events of 2025
F573	ALF/ACLF	Phase 2	Phase 2 clinical trial expected to be completed by December 2026
F528	Chronic Obstructive Pulmonary(COPD)	Preclinical	The IND submission is scheduled in December 2025
F230	Pulmonary Arterial Hypertension(PAH)	Phase 1 Received IND approval	Phase 1 clinical trial is scheduled in May 2025

*Schedule is based on current assumptions and is subject to change.

F351 Phase 3 Clinical Trial Results Received

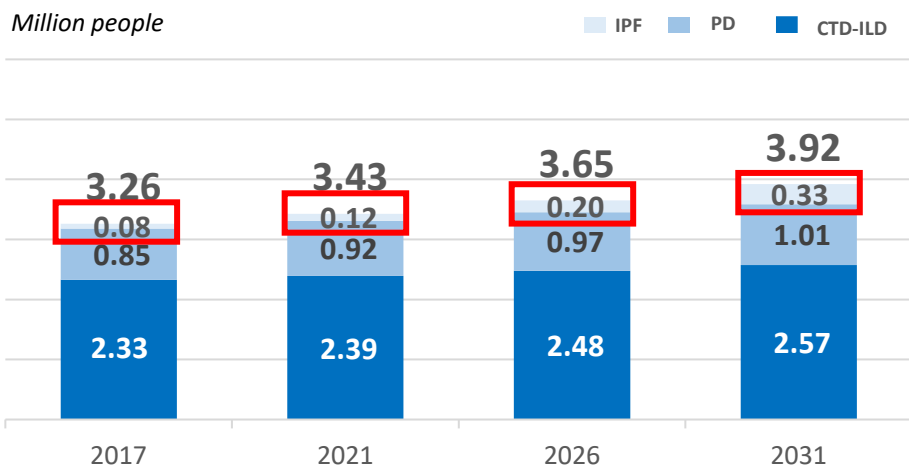
Schedule to the market

Events	Date
Completion of Phase 3 clinical trials	October 2024
Topline data disclosure	Awaiting the release of the analysis results
NDA application	2 to 3 months after data release if smooth
NDA approval	6 to 8 months after NDA if smooth

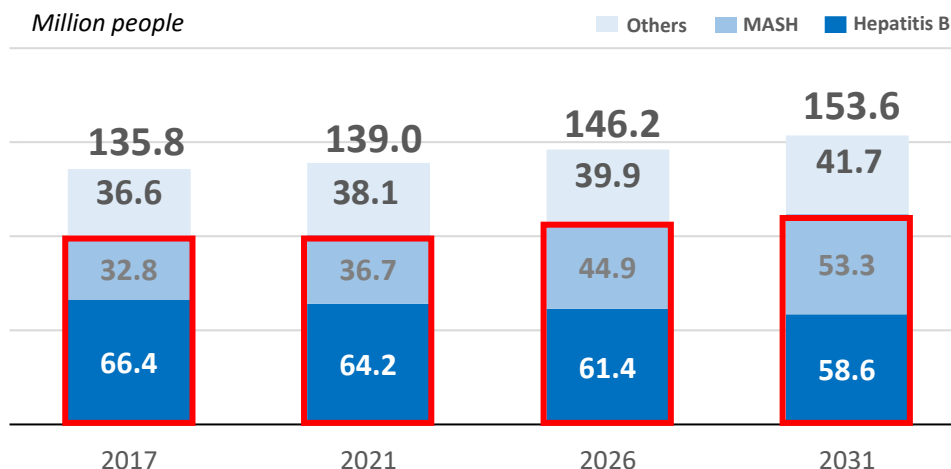
[Reference] Comparison of ETUARY[®] and F351

	ETUARY [®]	F351
Number of patients	Approx. 0.12 million (2021)	Approx. 100 million people (2021) Hepatitis B+MASH
Yearly cost per person	2 million yen	? ? ?
Revenue	15.6 billion yen (2024)	? ? ?

Trends in the Number of Pulmonary Fibrosis Patients in China

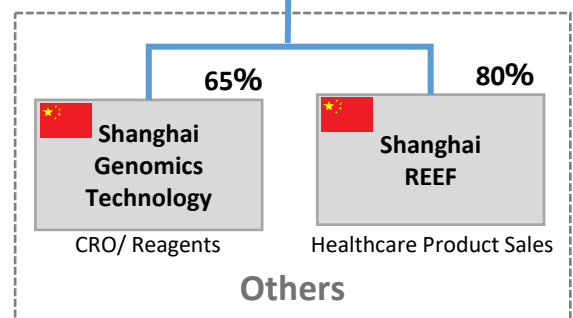
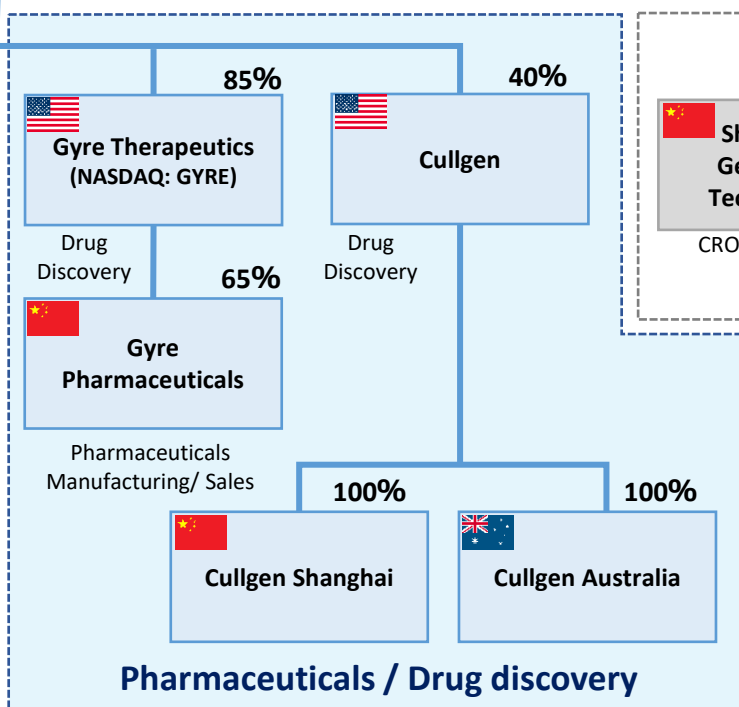
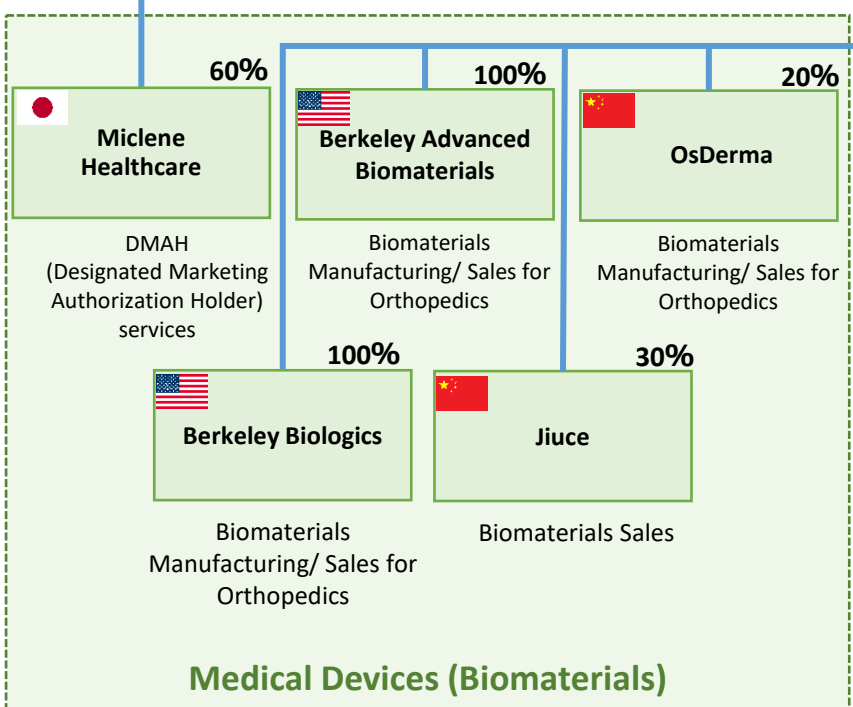
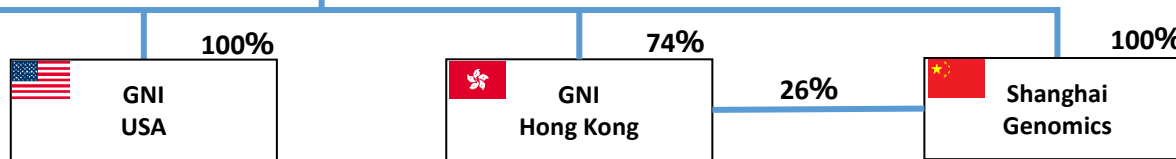


Trends in the Number of Liver Fibrosis Patients in China

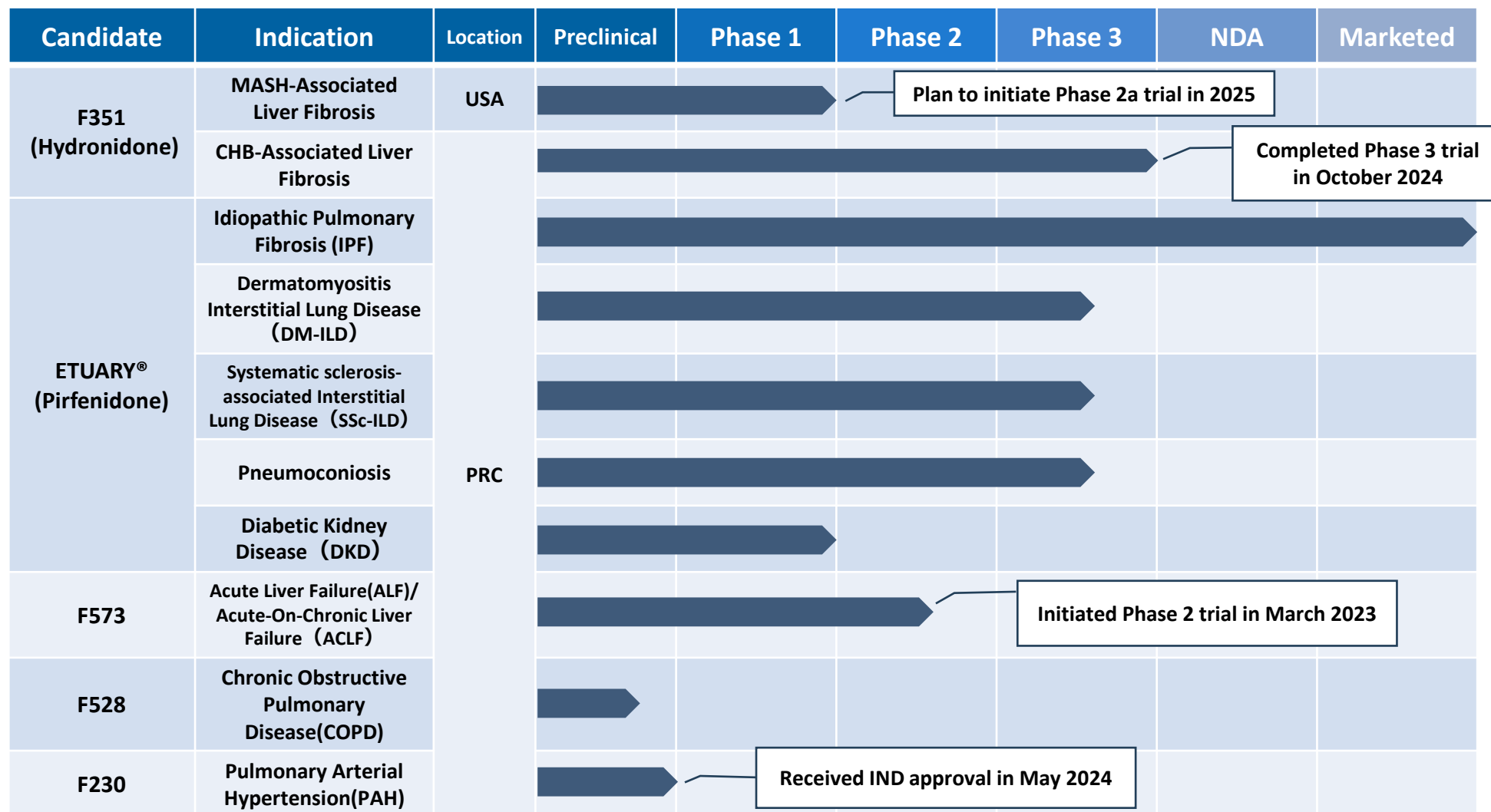


Source: Frost&Sullivan

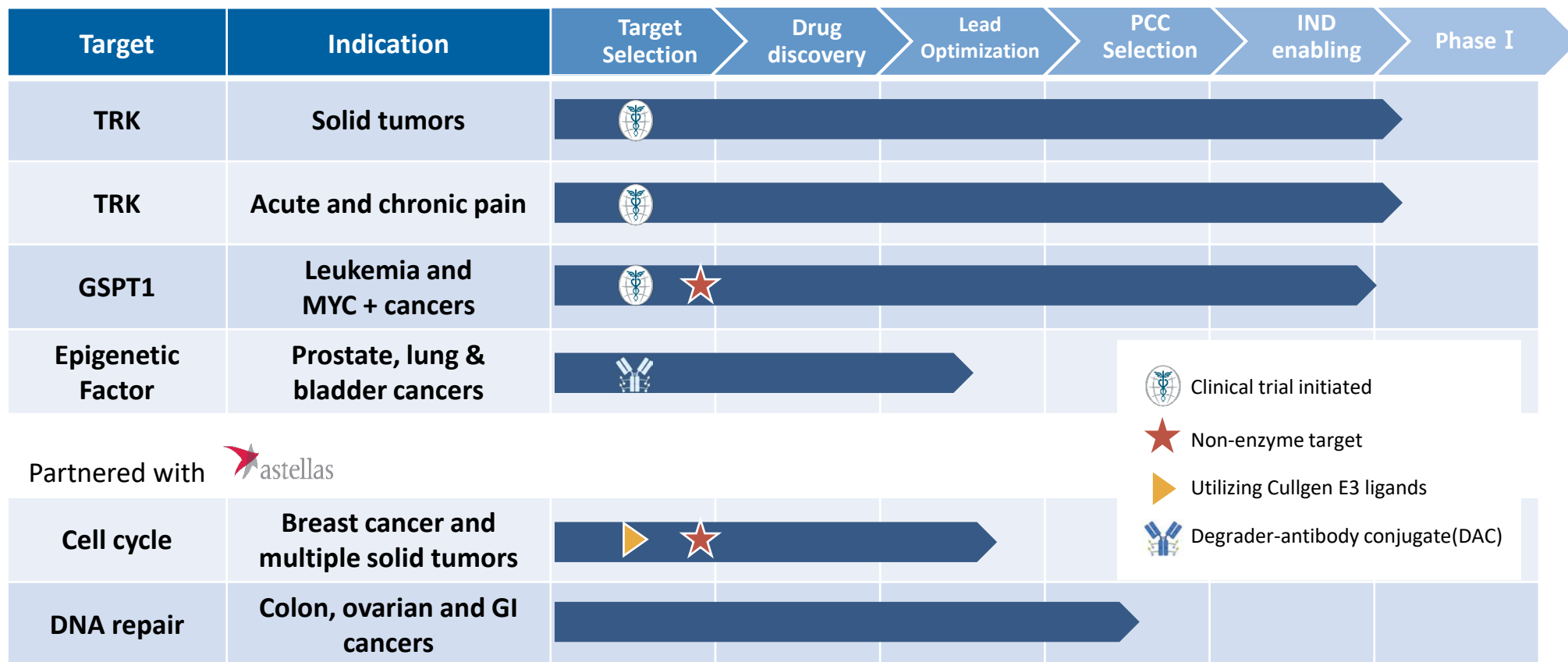
Group structure



Development Pipeline of Gyre Therapeutics & Gyre Pharmaceuticals



Development pipeline of Cullgen



"What Does the Future Hold for GYRE Based on The Market Capitalization Trends of Peer Companies?"

Company A

Date	Stock price	Market cap
Dec. 18, 2022 (Announced positive results from the phase 3 clinical trial)	63.8 USD	200 billion yen
Dec. 19, 2022	234.83 USD	765 billion yen
Then the higher price continues	368.29 USD	1.2 trillion yen



Market Cap as of October 18, 2024
197 billion JPY



Approx.
3.8 times



Company B

Date	Stock price	Market cap
Jan. 24, 2025	26.2 USD	300 billion yen
Jan 27, 2025 (Announced positive results from the phase 2b clinical trial)	51.7 USD	600 billion yen
Then the higher price continues	58.40 USD	667 billion yen



Approx.
2 times

When F351 Succeeds
? ? ?

*1USD = 150JPY

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