



# GNI Group Ltd. Financial Results for Q1 FY2024



**We Bring New  
Hope to Life.**

# Agenda

**1. Company Overview**

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**2. Financial Highlights**

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**3. Q1 FY2024 Topics**

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**4. Financial Forecats for FY2024**

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**5. FY2024 Topics**

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**6. GNI Group's Hidden Value**

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**7. Supplementary Materials**

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# 1. Company Overview

# Company Overview

## ■ Head Office

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

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## ■ Incorporation

November 2001

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## ■ Paid Capital

13,091 million yen (as of March 31, 2024)

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## ■ Listing

TSE Growth Market  
Listed in August 2007  
Securities code: 2160

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## ■ Main Business

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

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## ■ Director, Representative Executive Officer, President, and CEO

Ying Luo Ph.D.

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## ■ Number of Employees (group-wide)

847 (as of March 31, 2024)

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## ■ Operating Countries

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

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**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.

# Major subsidiaries

Area	Name	Business
Pharmatech	 <b>Gyre Therapeutics, Inc. (Gyre Therapeutics)</b>	<b>NASDAQ listed</b> Holding F351's non-Chinese rights Developing NASH therapeutics
	 <b>Gyre Pharmaceuticals Co., Ltd. (Gyre Pharmaceuticals)</b>	Operating drug discovery and pharmaceutical business in the PRC Having over 500 MR and building sales network Manufacturing and sales of ETUARY® Clinical development of F351 Full-scale entry into generic orphan drugs
Biotech	 <b>Cullgen Inc. (Cullgen)</b>	Operating drug discovery business in the U.S. and the PRC Collaboration, option, and license agreement with Astellas Pharma Inc. Received investment from AstraZeneca CICC Expecting to initiate operations in Australia <b>Preparing for listing opportunities</b>
Medtech (Biomaterials)	 <b>Berkeley Advanced Biomaterials LLC (BAB)</b>	Developing biomaterials business in the U.S. and the PRC (Aiming for business development in Japan as well) <b>Preparing for listing opportunities</b>
	 <b>Berkeley Biologics LLC (BB)</b>	

# Major Pharmaceutical & Drug Discovery

## <Pharmaceutical>

### ETUARY® (Commercial name : Pirfenidone)



- Chinese : 艾思瑞、 English : ETUARY®
- Treatment for idiopathic pulmonary fibrosis (IPF) **Dominant market share 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 (Commercial name : Hydronidone)



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

### Targeted Protein Degradar



- 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

\*Non-Alcoholic Steatohepatitis

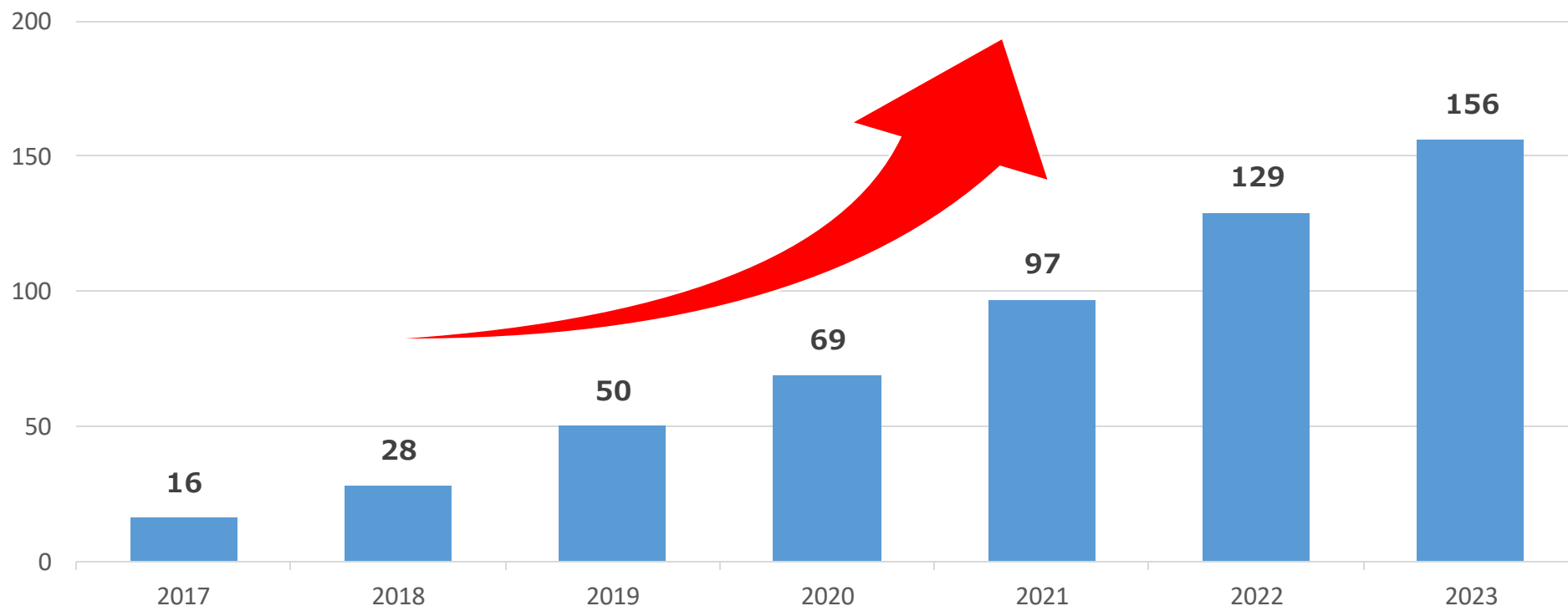


## Who we are (1)

# From Drug Discovery Success to Pharmaceuticals

## ETUARY® Sales

(100 million yen)

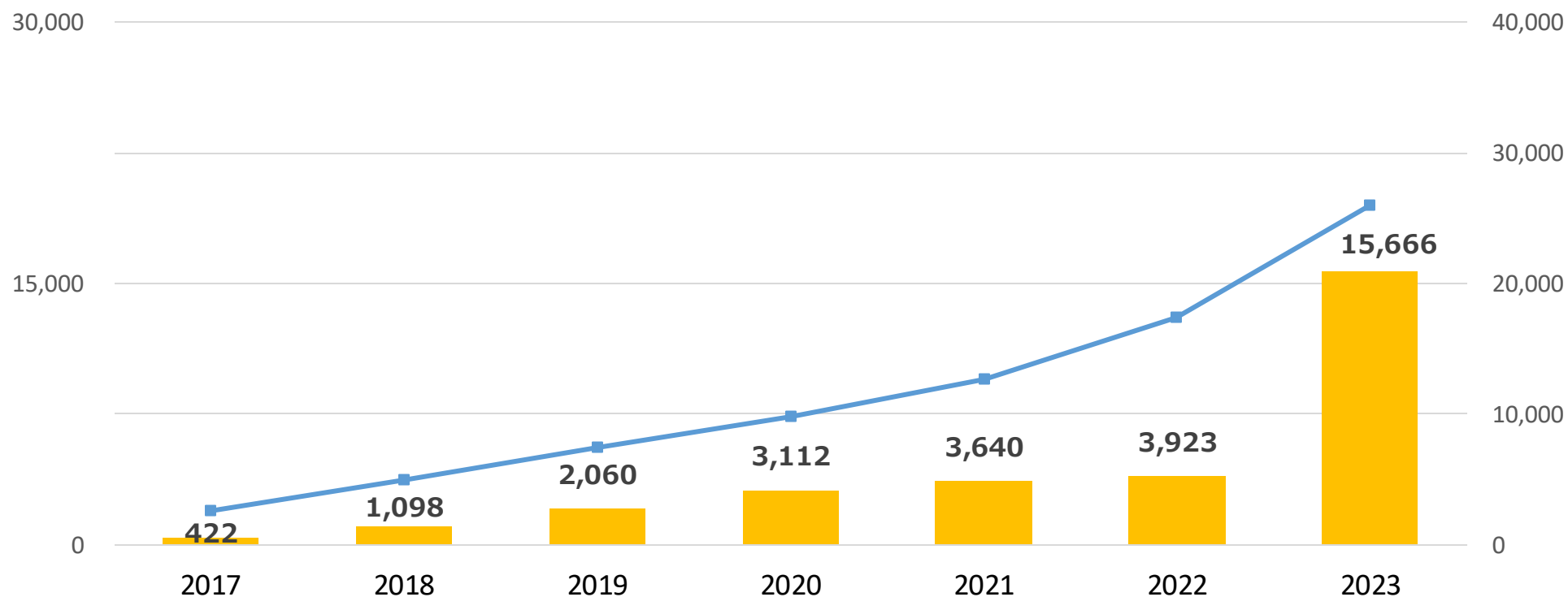


## Who we are (2)

# A Rare, Profitable Drug Discovery Company

(Millions of yen)

■ Operating profit before R&amp;D\* (left axis) — Revenue (right axis)



\* Operating profit before R&amp;D = Operating profit + R&amp;D expenses

## Who we are (3)

**Globally recognized for high development capabilities**

**Successful development of ETUARY<sup>®</sup>**

**Satisfactory safety profile for F351\***

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

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

\*Phase 2 clinical trial results are detailed in the supplementary materials.

Who we are (4)

**Holding a NASDAQ listed subsidiary**

**Extremely rare among Japanese TSE listed companies  
to have a **NASDAQ listed company\*** as a subsidiary**

**\*Gyre Therapeutics, Inc.**

**GNI Group is a group company that**

- **Operates globally in the U.S. and the PRC 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 unlimited growth potential under the vision of "We Bring New Hope to Life".**

In other words,

## GNI Group

maintains strong growth  
(**Growth stock**)

while possessing many assets  
and a facet of an under-valued stock  
(**Value stock**).

## 2. Financial Highlights

# Income statement summary

**Record-high in revenue and profit in the first quarter**

Millions of yen	Q1 FY2023 Cumulative total	Vs. revenue	Q1 FY2024 Cumulative total	Vs. revenue	Inc. / (Dec.)
<b>Revenue</b>	<b>4,206</b>	<b>100.0%</b>	<b>5,948</b>	<b>100.0%</b>	<b>41.4%</b>
<b>Gross profit</b>	<b>3,632</b>	<b>86.4%</b>	<b>4,731</b>	<b>79.5%</b>	<b>30.2%</b>
Selling, general and administrative expenses	2,646	62.9%	3,288	55.3%	24.3%
R&D	635	15.1%	688	11.6%	8.4%
<b>Operating profit</b>	<b>397</b>	<b>9.5%</b>	<b>2,283</b>	<b>38.4%</b>	<b>474.4%</b>
<b>Income before income taxes</b>	<b>(64)</b>	<b>(1.5)%</b>	<b>1,827</b>	<b>30.7%</b>	<b>-</b>
<b>Net income</b>	<b>(341)</b>	<b>(8.1)%</b>	<b>1,344</b>	<b>22.6%</b>	<b>-</b>
<b>Profit attributable to owners of parent</b>	<b>(2)</b>	<b>(0.1)%</b>	<b>1,454</b>	<b>24.5%</b>	<b>-</b>



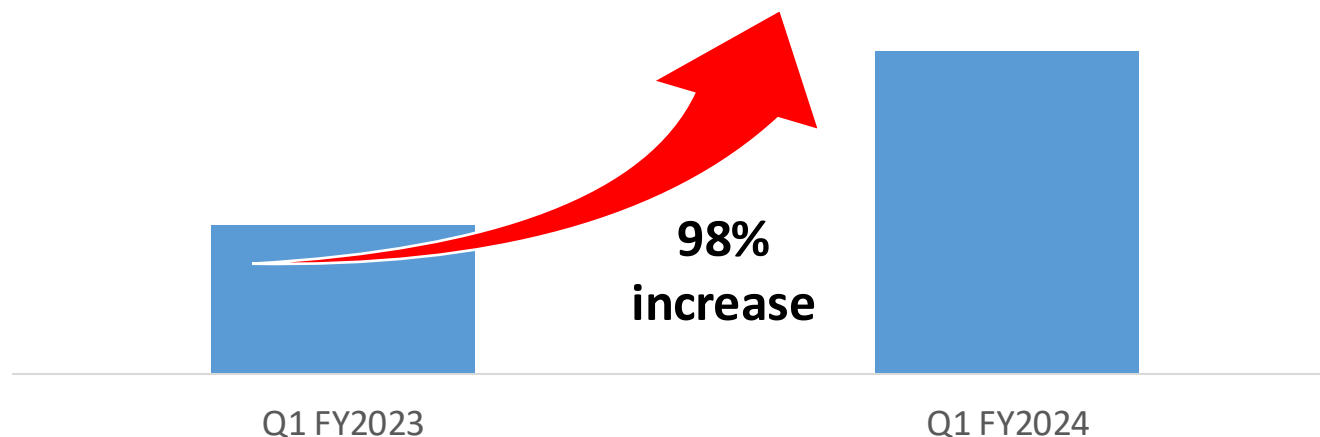
# Balance sheet summary

## Retained earnings increased significantly due to profit boost

Millions of yen	FY2021 End Actual	FY2022 End Actual	FY2023 End Actual	Q1 FY2024 Cumulative total	Inc. / (Dec.)
Total non-current assets	12,109	16,759	31,487	33,620	6.8%
<b>Total current assets</b>	<b>18,187</b>	<b>17,147</b>	<b>30,907</b>	<b>31,979</b>	<b>3.5%</b>
<b>Total assets</b>	<b>30,296</b>	<b>33,906</b>	<b>62,394</b>	<b>65,600</b>	<b>5.1%</b>
Total non-current liabilities	8,487	10,592	18,147	17,082	(5.9)%
Total current liabilities	2,543	3,503	8,193	10,763	31.4%
<b>Total liabilities</b>	<b>11,030</b>	<b>14,096</b>	<b>26,341</b>	<b>27,845</b>	<b>5.7%</b>
Capital and other	17,108	17,125	20,434	19,356	(5.3)%
<b>Retained earnings</b>	<b>307</b>	<b>696</b>	<b>8,790</b>	<b>10,245</b>	<b>16.5%</b>
Other components of equity	1,444	3,147	4,569	4,986	9.1%
<b>Equity attributable to parent</b>	<b>18,860</b>	<b>20,969</b>	<b>33,794</b>	<b>34,587</b>	<b>2.3%</b>
Non-controlling interests	405	(1,158)	2,258	3,166	40.2%
Total shareholders' equity	19,266	19,810	36,052	37,754	4.7%

## Ample cash

**12.5 billion yen**      **24.8 billion yen**



### Current Assets

Cash and cash equivalents	<b>10.5 billion yen</b>	<b>20.3 billion yen</b>
Time Deposits	<b>190 million yen</b>	<b>1.11 billion yen</b>

### Non-Current Assets

Long-term Deposits	<b>1.78 billion yen</b>	<b>3.41 billion yen</b>
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# R&D expenses

## Making steady progress

(Millions of yen)

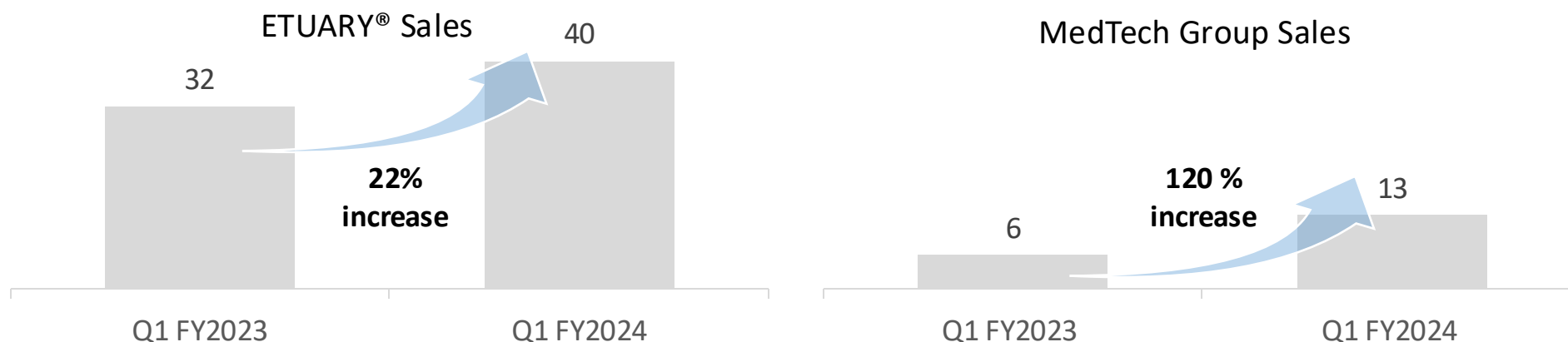
	FY2021 Actual	FY2022 Actual	FY2023 Actual	Q1 FY2024 Cumulative total
Consolidated R&D expenses	2,015	2,545	2,557	688
Capitalized development costs	336	606	940	258
<b>Total</b>	<b>2,351</b>	<b>3,151</b>	<b>3,497</b>	<b>947*</b>

\*27% YoY increase

## 3. Q1 FY2024 Topics

## Solid progress in the segments

(100 million yen)



## Expecting for further acceleration



# Supplementary Generic Orphan Drug\* Pipeline

## Enhancement of sales pipeline

Products under development

**Avatrombopag Maleate Tablets**

Indication: Thrombocytopenia due to chronic liver disease

**Fingolimod Hydrochloride Capsules**

Indication: Multiple sclerosis

\*The prices of orphan drugs in the PRC are high and stable.



# Acquisition of rights to other pulmonary fibrosis drug Nintedanib to

(May 2024)

**consolidate leading position in fibrosis**

||

**Responding to the needs for  
non-IPF pulmonary fibrosis**

**Bringing in additional revenue / profit  
in 2024 and beyond**

**Efficient use of nationwide sales network**

# Expanding the business to Australia

**4th operating countries**  
after Japan, the U.S., and the PRC

**Accelerating the submission of  
IND application**



# Toward the establishment of a new investment arm to seed future growth

**Purpose : Future profit opportunities**

1. Profits into PL
2. Proceeds from sale

**Method : Investment through fund**

||

Minimizing impact on PL & BS

## **Business alliance with Governance Partners Inc.**

### **Speeding up the investment segment**

1. Accelerating M&A and search for potential investment targets (incl. listed companies)
2. Strengthening value of portfolio companies

## Joint fund formation

Concluded the agreement\* aiming to establish  
**US\$100 million industrial development** fund

1. Investment in a wide range of cutting-edge technologies including AI
2. Investment in healthcare sector

\*Parties: GNI, Wuxi Binhu City Industrial Development Group Co., Ltd.,  
and Wuxi Capital Group Co., Ltd.

Details of the fund including investment amount will be determined  
after negotiation among the companies.

## **Business alliance with alt Inc.**

### Utilizing AI for drug discovery and investment

Utilizing AI for the following purposes

1. Assist in remote diagnosis
2. Facilitate clinical development
3. Expand access to future technology

## 4. Financial Forecasts for FY2024

# Financial forecasts for FY2024

**Aiming for significant increase in revenue and profit  
for the second consecutive year**

(Millions of yen)	FY2023 Actual	FY2024 Forecast	Inc. / (Dec.)
Revenue	26,010	39,556	52.1%
Gross profit	22,431	34,624	54.4%
Operating profit	13,108	16,286	24.2%
Income before income taxes	12,612	15,552	23.3%
Net income	9,504	12,287	29.3%
Profit attributable to owners of parent	8,094	7,058	(12.8)%

## 5. FY2024 Topics

## Path to the future

1. Officially announced\* the preparation to move to the **Prime Market**
2. Aiming to be selected in **JPX indices**

Goal of FY2024: JPX-Nikkei Mid and Small Cap Index

Goal after FY2025: JPX-Nikkei Index 400 Index

\*For more information, please refer to the release dated on May 15, 2024



# Expansion of operation in Japan

through synergistic M&A



**Establishment of domestic sales**

**Striking the area balance**

# Revenue expansion and global rollout

- 1. F351** in the PRC / Phase 3 **To complete clinical development**
- 2. NASH** in the PRC / Phase 3  
in the U.S. / Phase 2a **To prepare for future clinical development**
- 3. Operations in Australia**
- 4. Enhancement of product pipeline**

# Preparing for Cullgen's listing

**Increased GNI Group's ownership**  
**31% → 40%**

Voyagers Capital Partners I: net investment -> subsidiary (2023)  
Obtained from CVI Investments, Inc. (2024)

# New CEO was appointed in the MedTech Group

Aiming to achieve  
US\$100 million in revenue



**IPO**

## 6. GNI Group's Hidden Value

## Point: Book value versus market value

### Book value

### Current Value

**Gyre Therapeutics\***  
**(incl. Gyre Pharmaceuticals)**

**13.0 billion yen**

**180.8 billion yen**  
**(GNI owned portion)**

\* Listed on NASDAQ

Madrigal Pharmaceuticals Inc. (a competitor) market cap: 703.2 billion yen

※Based on May 14, 2024 close

**Cullgen**

**7.3 billion yen**

**???** billion yen

Arvinas, Inc. (a competitor) market cap: 335.6 billion yen

※Based on May 14, 2024 close

**MedTech Group (BAB + BB)**

**8.5 billion yen**

**???** billion yen

Q1 FY2024

Revenue 1.3 billion yen

Op. Profit 530 million yen

FY2023

Revenue 2.7 billion yen

Op. Profit 1.33 billion yen

## Point: GNI Group's Hidden Value

**GNI market cap** **122.3 billion yen**

**GYRE market cap** **212.0 billion yen**

※ Based on May 14, 2024 close

**Net cash** **18.9 billion yen**

**Gyre (GNI-owned portion)** **180.8 billion yen**

**Cullgen** **??? billion yen**

**MedTech Group (BAB + BB)** **??? billion yen**

**What is the fair market value?**

## Point: Market value-based PBR

# GNI market cap 122.3 billion yen

Book Value Basis (BS)		Market value basis	
Assets 65.6 billion yen	Liabilities 27.8 billion yen	Market value of assets <b>246.4 billion yen</b> + ???	Liabilities 27.8 billion yen
	Net assets 34.5 billion yen Non-controlling interests 3.1 billion yen		Net assets at market value <b>215.5 billion yen</b> Non-controlling interests 3.1 billion yen + ???

Market-value based PBR:  $1,223 / 2,155 = 0.56$

**= Well below 1**

※ Based on May 14 2024 close



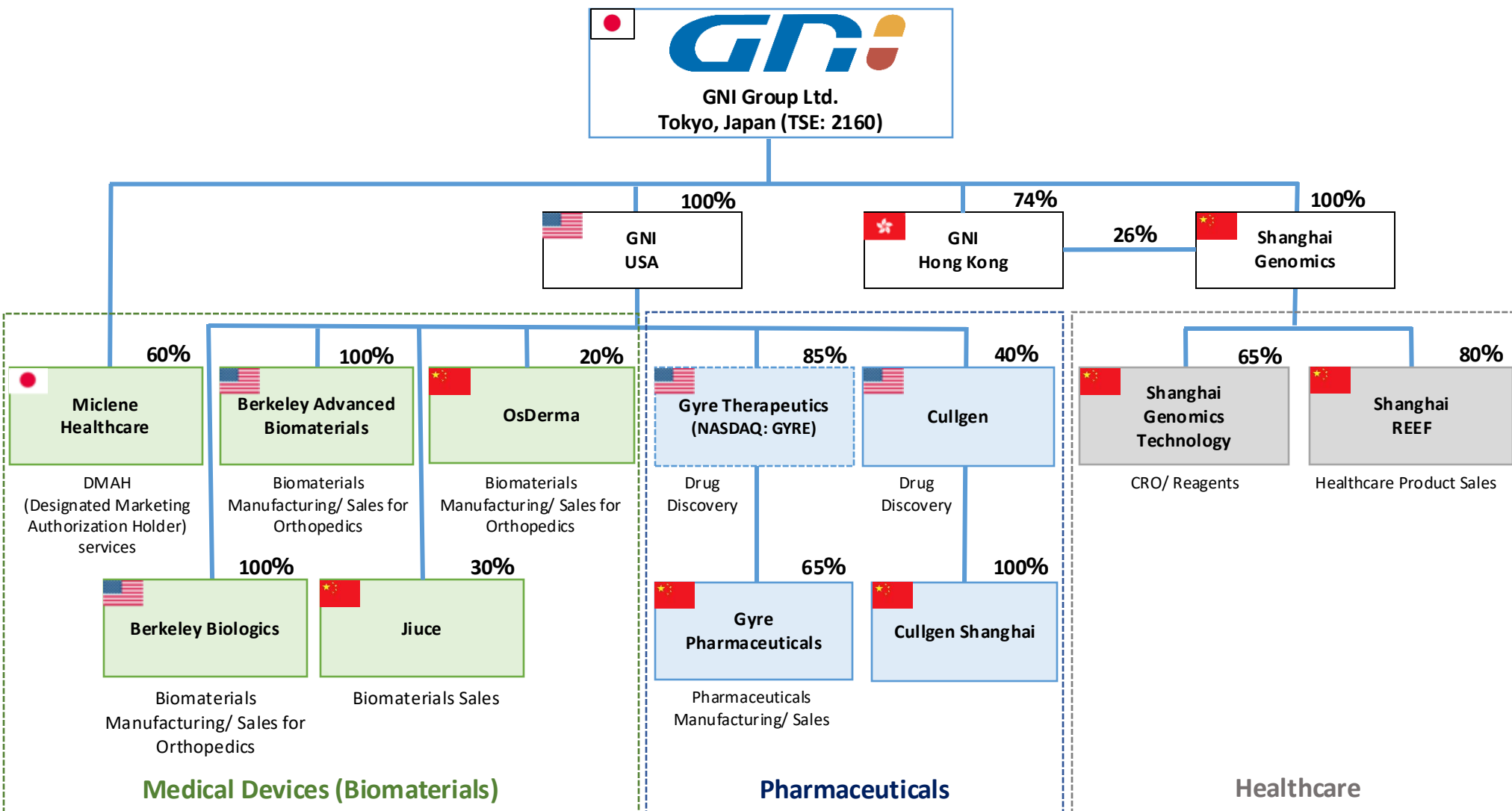
# GNI Group

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## 7. Supplementary Materials

# Group structure



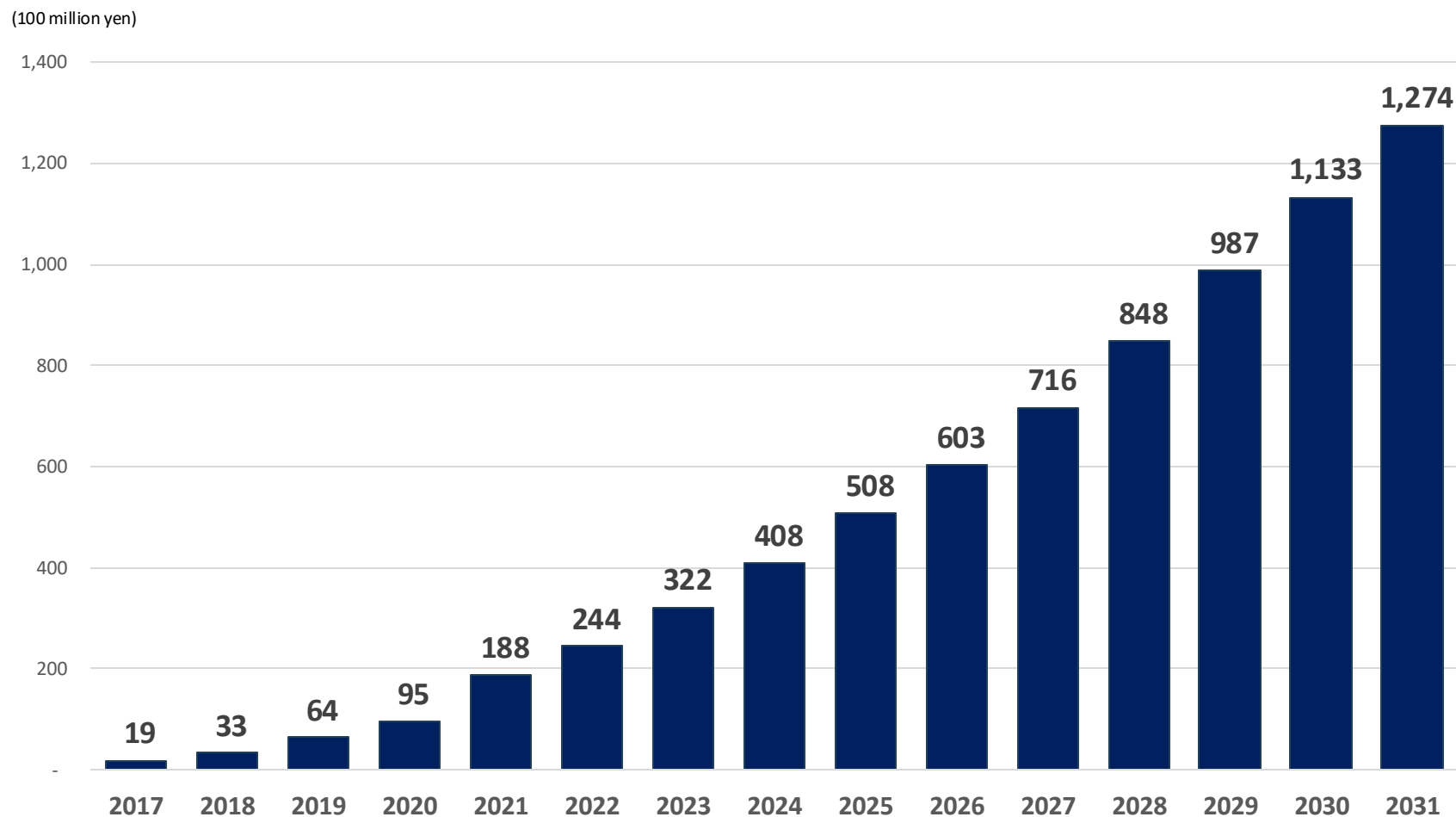
# Development Pipeline of Gyre Therapeutics & Gyre Pharmaceuticals

Candidate	Indication	Preclinical	Phase 1	Phase 2	Phase 3	Marketed	Location
F351 (Hydronidone)	NASH-Associated Liver Fibrosis	[Progress bar]			Plan to initiate Phase 2a trial in 2025		USA
	CHB-Associated Liver Fibrosis	[Progress bar]			Completed enrollment of patients in October 2023		
ETUARY® (Pirfenidone)	Idiopathic Pulmonary Fibrosis (IPF)	[Progress bar]					PRC
	Dermatomyositis Interstitial Lung Disease (DM-ILD)	[Progress bar]					
	Systemic Sclerosis-associated Interstitial Lung Disease (SSc-ILD)	[Progress bar]					
	Pneumoconiosis	[Progress bar]					
	Diabetic Kidney Disease (DKD)	[Progress bar]					
F573	ALF/ACLF	[Progress bar]			Initiated Phase 2 trial in March 2023		
F528	Chronic Obstructive Pulmonary Disease (COPD)	[Progress bar]					
F230	Pulmonary Arterial Hypertension (PAH)	[Progress bar]	Submitted IND application in March 2024				

# Development pipeline of Cullgen



## Market size of ETUARY®: Idiomatic Pulmonary Fibrosis (IPF) drug market in the PRC



Source: Frost & Sullivan (converted to JPY by GNI)

# F351 Phase 2 trial top-line data overview (1/3)

## Efficacy Results

Efficacy Analyses	Placebo	F351: 60mg/dose 3 doses/day	F351: 90mg/dose 3 doses/day	F351: 120mg/dose 3 doses/day		
Ishak score down by 1+ As of 52nd week (FAS)	11 (11/43, 25.58%)	17 (17/42, 40.48%)	23 (23/41, 56.10%)	18 (18/41, 43.90%)		
Ishak score down by 1+ As of 52nd week (PPS)	11 (11/42, 26.19%)	17 (17/36, 47.22%)	23 (23/35, 65.71%)	18 (18/34, 52.94%)		
p value	FAS: 0.0245, PPS: 0.0058					
Ratio Difference (Placebo - F351)% & 95% CI	FAS:		FAS:		FAS:	
	-14.89 (-33.32, 4.99)		-30.52 (-48.12, -9.50)		-18.32 (-36.76, 1.96)	
	PPS:		PPS:		PPS:	
	-21.03 (-40.20, 0.26)		-39.52 (-56.83, -17.26)		-26.75 (-45.78, -4.75)	

Source: GNI Group disclosure dated on October 23, 2020

## F351 Phase 2 trial top-line data overview (2/3)

Efficacy results: additional analyses for patients with Ishak score = 6 (cirrhosis stage)

Efficacy analyses	Placebo	F351 (all groups)
Ishak score decreased by $\geq 1$ point after 52 weeks treatment (FAS)	1 (1/4, 25%)	12 (12/15, 80%)
Ishak score decreased by $\geq 1$ point after 52 weeks treatment (PPS)	1 (1/4, 25%)	12 (12/14, 85.71%)
p value	FAS: 0.0407, PPS: 0.0201	
Ratio Difference (Placebo - F351)% & 95% CI	FAS:	
	-55.00 (-79.20, -3.49)	
	PPS:	
	-60.71 (-83.59, -8.97)	

Source: GNI Group disclosure dated on October 23, 2020



## F351 Phase 2 trial top-line data overview (3/3)

### Safety and tolerability results

- ✓ **Adverse Events severity: mild to moderate**
  
- ✓ **Serious Adverse Events incident rate: same among the groups**
  - **Placebo: 4.65%**
  - **F351: 60mg/dose, 3 doses/day group: 2.38%**
  - **F351: 90mg/dose, 3 doses/day group: 2.38%**
  - **F351: 120mg /dose, 3 doses/day group: 7.32%**
  
- ✓ **No fatalities in the trial**

Source: GNI Group disclosure dated on October 23, 2020

# Contact Info:

## GNI Group Ltd.

### Investor Relations

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 : [www.gnipharma.com](http://www.gnipharma.com)

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