



# GNI Group Ltd. Financial Results for Q2 FY2024

**We Bring New  
Hope to Life.**

# Agenda

**1. Company Overview**

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**2. Financial Highlights**

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**3. Q2 FY2024 Topics**

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**4. Financial Forecasts for FY2024**

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**5. Second Half of 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

13,218 million yen (as of Jun 30, 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)

960 (as of Jun 30, 2024)

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## ■ Operating Countries

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

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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.

Business model	Pharmatech	Biotech	Medtech (Biomaterials)
<b>Name</b>	 <b>Gyre Therapeutics, Inc.</b>  <b>Gyre Pharmaceuticals</b>	 <b>Cullgen Inc.</b>	 <b>Berkeley Advanced Biomedicals LLC (BAB)</b>  <b>Berkeley Biologics LLC (BB)</b>
<b>Topics</b>	<ul style="list-style-type: none"> <li>Listed on NASDAQ</li> <li>Development of anti-fibrotic and anti-inflammation drugs</li> <li>Manufacturing and commercialization (ETUARY® and others)</li> </ul>	<ul style="list-style-type: none"> <li>Drug discovery platform (TPD) in cancers and others</li> <li>Research Collaboration (Astellas Pharma)</li> <li>Received investment from AstraZeneca</li> </ul>	<ul style="list-style-type: none"> <li>M&amp;A executed last year</li> </ul>
<b>FY2023 Revenue/ Operating profit</b>	BC: 15.7 billion yen 3.99 billion yen	5.8 billion yen 2.69 billion yen	2.74 billion yen 1.33 billion yen
<b>Q2 FY2024 Revenue</b>	7.38 billion yen (Q2 FY2023) ↓ 7.84 billion yen	0 yen*(Q2 FY2023) ↓ *Received 4.72 billion yen as an upfront payment from Astellas Pharma 750 million yen *Next milestone (additional)	1.23 billion yen (Q2 FY2023) ↓ 2.53 billion yen
<b>FY2024 Forecasts</b>	<ul style="list-style-type: none"> <li>F351 clinical trial results</li> <li>Commercialization of other orphan drugs acquired in 2024</li> </ul>	<ul style="list-style-type: none"> <li>NASDAQ listing</li> <li>Approx. 2 million yen in profit in 2023</li> <li>Aiming for the next milestone</li> <li>Prepare for listing in 2024</li> </ul>	<ul style="list-style-type: none"> <li>New CEO from J&amp;J joined</li> <li>Expecting to nearly double sales this fiscal year</li> <li>Prepare for future listing</li> </ul>

# 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 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 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 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

**1 IND filed and 1 phase 1 ongoing**

\*Non-Alcoholic Steatohepatitis

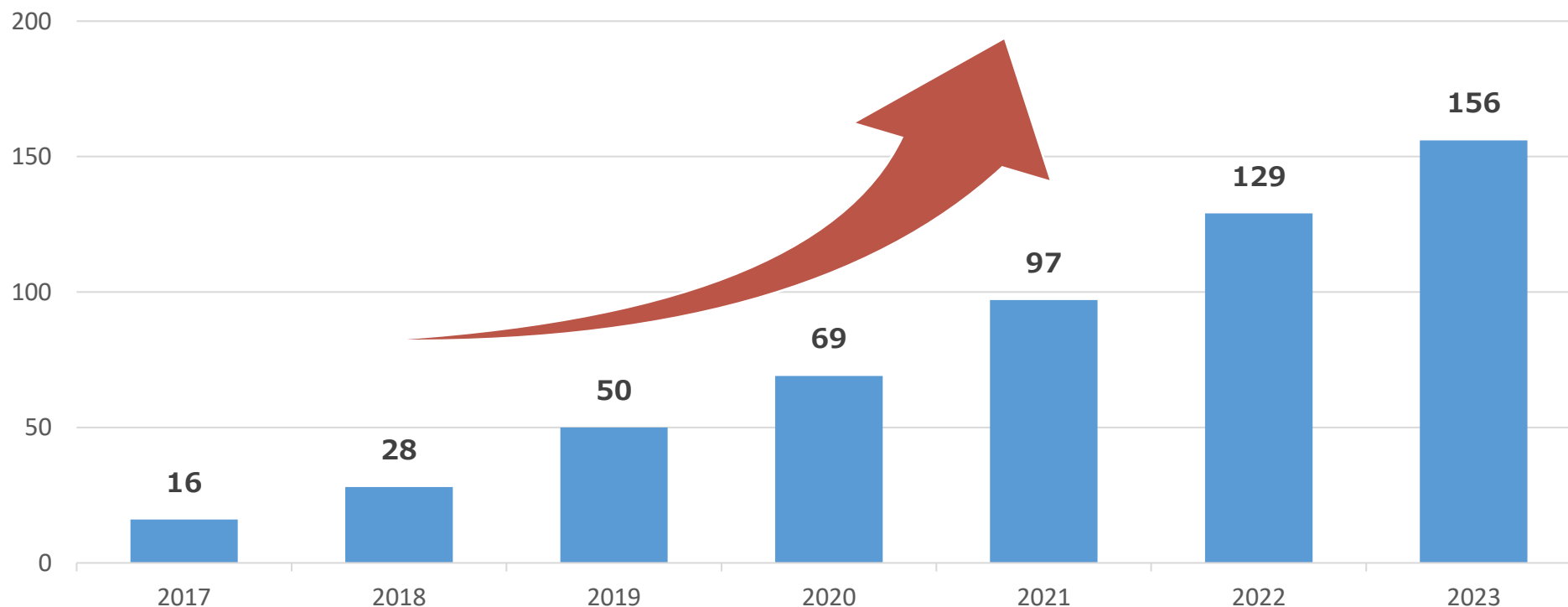


## Who we are (1)

# From Drug Discovery Success to Pharmaceuticals

## ETUARY® Sales

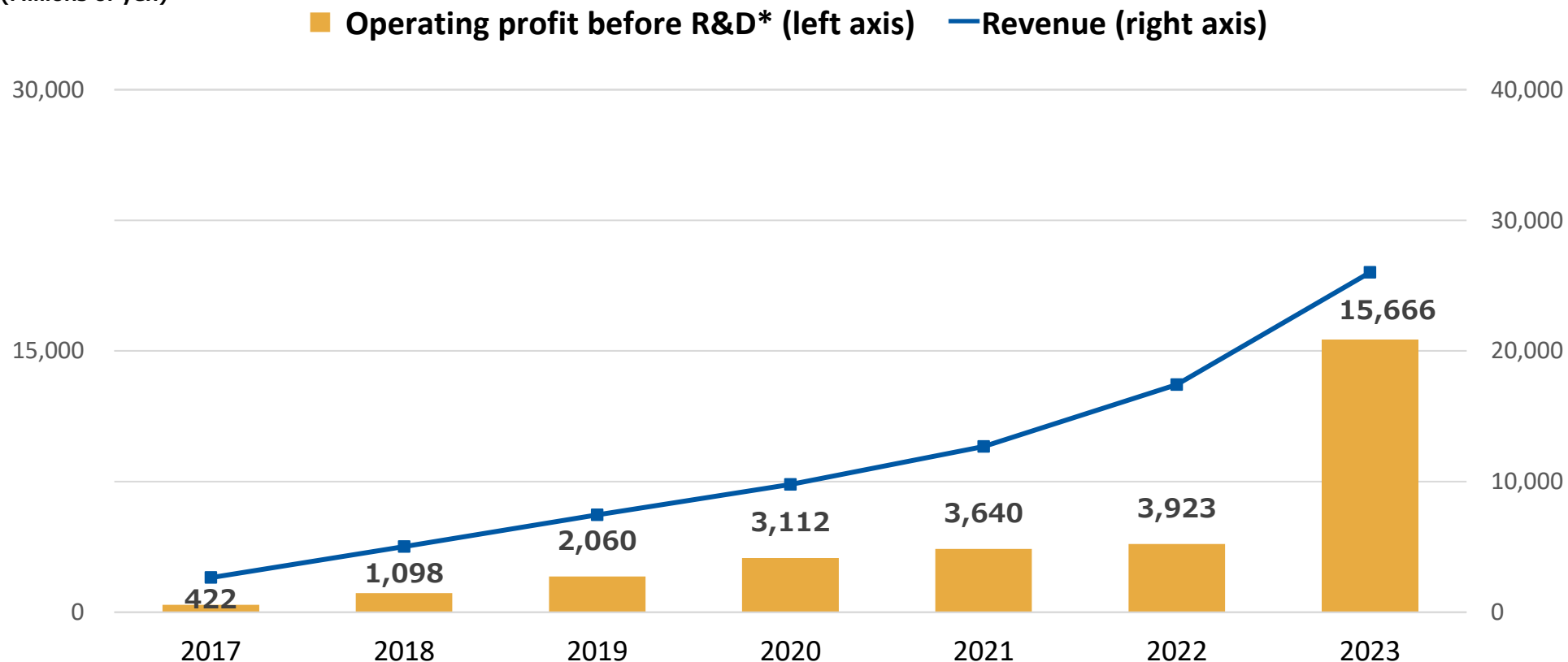
(100 million yen)



## Who we are (2)

# A Rare Drug Development Company With Commercialization Capability and Operating Profit

(Millions of yen)



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

## Who we are (3)

**Globally recognized for high development capabilities**

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

**Near completion of Phase 3 trial 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)

# 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 will come up in the future listing**
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

# Income statement summary

Although the core business is doing well, a temporary loss has occurred on the accounting base.

Millions of yen	Q2 FY2023 Cumulative total	Vs. revenue	Q2 FY2024 Cumulative total	Vs. revenue	Inc. / (Dec.)	(Ref.) Gyre* Q2 FY2024 total
<b>Revenue</b>	<b>14,096</b>	<b>100.0%</b>	<b>11,733</b>	<b>100.0%</b>	<b>(16.8)%</b>	<b>7,982</b>
<b>Gross profit</b>	<b>12,755</b>	<b>90.4%</b>	<b>9,568</b>	<b>81.5%</b>	<b>(25.0)%</b>	-
Selling, general and administrative expenses	6,179	43.8%	7,117	60.6%	15.2%	-
R&D	1,253	8.8%	1,419	12.0%	13.3%	-
<b>Operating profit</b>	<b>5,476</b>	<b>38.8%</b>	<b>1,762</b>	<b>15.0%</b>	<b>(67.8)%</b>	<b>2,821</b>
<b>Finance cost</b>	<b>539</b>	<b>3.8%</b>	<b>1,343</b>	<b>11.4%</b>	<b>149.1%</b>	-
<b>Income before income taxes</b>	<b>5,117</b>	<b>36.3%</b>	<b>831</b>	<b>7.0%</b>	<b>(83.8)%</b>	-
<b>Net income</b>	<b>4,014</b>	<b>28.4%</b>	<b>(73)</b>	<b>(0.6)%</b>	<b>(101.8)%</b>	2,205
<b>Profit attributable to owners of parent</b>	<b>1,658</b>	<b>11.7%</b>	<b>330</b>	<b>2.8%</b>	<b>(80.1)%</b>	-

\*Source: Gyre Therapeutics' financial disclosure



## Details of temporary losses (accounting based, non-cash)

### Breakdown

### Countermeasure

#### ① Other expences

Stock valuation loss related to stock forward contract with Macquarie

**:1,044 million yen**



**Expected to be resolved by increasing corporate value through events in the second half of 2024 (refer to p.30)**

#### ② Finance costs

Exchange loss relating to the Gyre reverse merger transaction

**:1,093 million yen** (exchange rate as of Jun 30: 161.07 yen)



**Resolution to be announced in Q3 FY2024**

**Total temporary losses (accounting based)**

**:2,137 million yen**

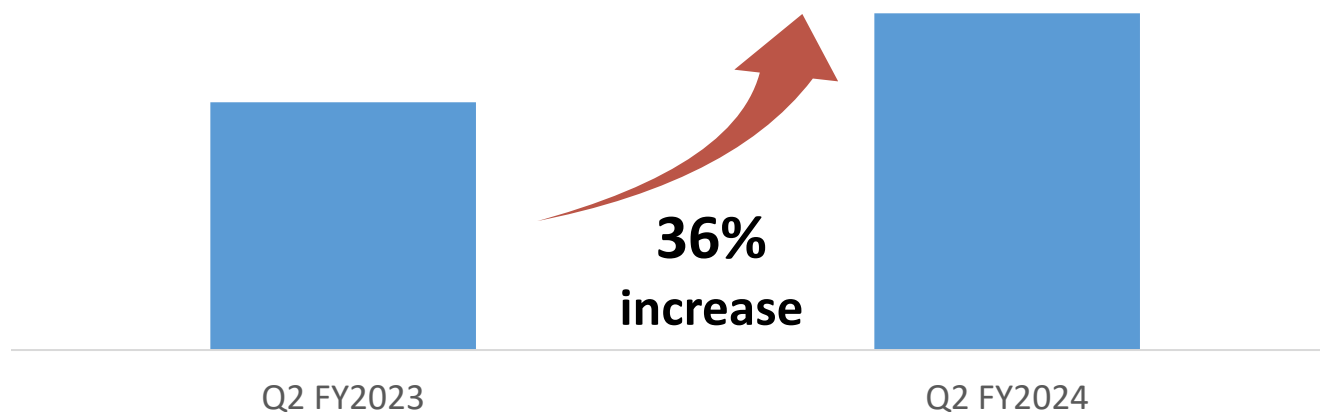
# Balance sheet summary

Millions of yen	FY2021 End Actual	FY2022 End Actual	FY2023 End Actual	Q2 FY2024 Cumulative total	Inc. / (Dec.)
Total non-current assets	12,109	16,759	31,487	38,145	21.1%
<b>Total current assets</b>	<b>18,187</b>	<b>17,147</b>	<b>30,907</b>	<b>30,847</b>	<b>(0.2)%</b>
<b>Total assets</b>	<b>30,296</b>	<b>33,906</b>	<b>62,394</b>	<b>68,993</b>	<b>10.6%</b>
Total non-current liabilities	8,487	10,592	18,147	18,512	2.0%
Total current liabilities	2,543	3,503	8,193	10,916	33.2%
<b>Total liabilities</b>	<b>11,030</b>	<b>14,096</b>	<b>26,341</b>	<b>29,429</b>	<b>11.7%</b>
Capital and other	17,108	17,125	20,434	19,684	(3.7)%
<b>Retained earnings</b>	<b>307</b>	<b>696</b>	<b>8,790</b>	<b>9,120</b>	<b>3.8%</b>
Other components of equity	1,444	3,147	4,569	8,029	75.7%
<b>Equity attributable to parent</b>	<b>18,860</b>	<b>20,969</b>	<b>33,794</b>	<b>36,834</b>	<b>9.0%</b>
Non-controlling interests	405	(1,158)	2,258	2,729	20.8%
Total shareholders' equity	19,266	19,810	36,052	39,564	9.7%

## Sufficient cash

**16.9 billion yen**

**23 billion yen**



### Current Assets

Cash and cash equivalents

**14.0 billion yen**

**16.3 billion yen**

Time Deposits

**190 million yen**

**2.19 billion yen**

### Non-Current Assets

Long-term Deposits

**2.66 billion yen**

**4.52 billion yen**

# R&D expenses

## Making steady progress

(Millions of yen)

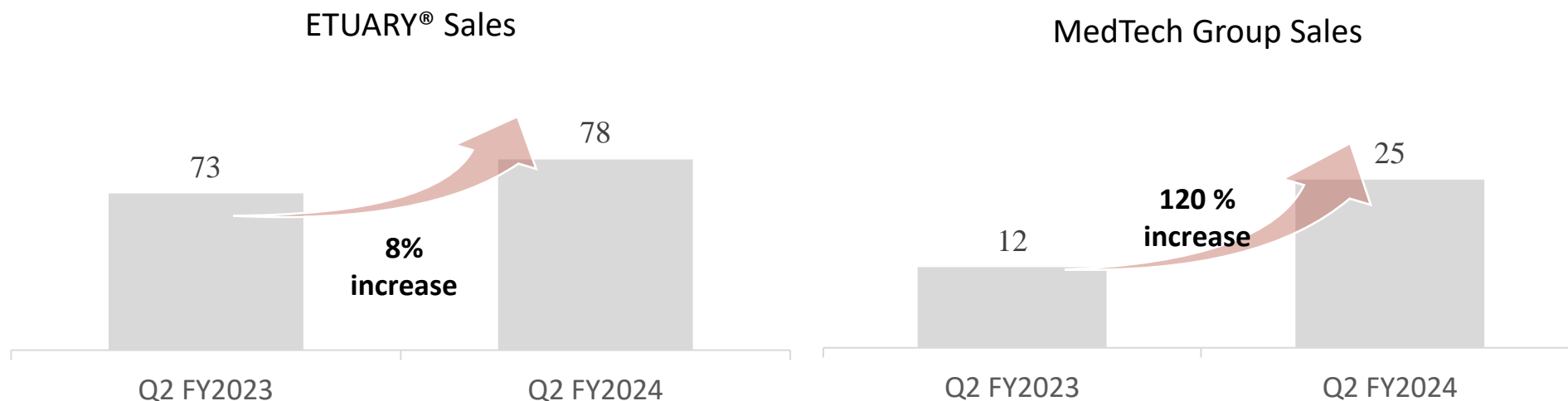
	FY2021 Actual	FY2022 Actual	FY2023 Actual	Q2 FY2024 Cumulative total
<b>Consolidated R&amp;D expenses</b>	<b>2,015</b>	<b>2,545</b>	<b>2,557</b>	<b>1,419</b>
<b>Capitalized development costs</b>	<b>336</b>	<b>606</b>	<b>940</b>	<b>568</b>
<b>Total</b>	<b>2,351</b>	<b>3,151</b>	<b>3,497</b>	<b>1,987*</b>

\*13% YoY increase

## 3. Q2 FY2024 Topics

# Solid progress in the Segments

(100 million yen)



**For the further expansion**



# New products expected to commercialize in 2024

## 1. Nintedanib

- **Production and sales rights acquired (May 2024)**
- Indications: IPF, systemic sclerosis-associated interstitial lung disease (SSc-ILD) and progressive fibrotic interstitial lung disease (PF-ILD)
- There are only two drugs in the world for pulmonary fibrosis: pirfenidone (ETUARY®) and Nintedanib. GYRE has both to provide one-stop solution

## 2. Avatrombopag Maleate

- **Sales approval acquired (Jun 2024)**
- Indications: Thrombocytopenia due to chronic liver disease
- Orphan drugs

# Ongoing research and development



IND (Investigative Drug Application) approved (May 2024)

**F230**

- Indication: Pulmonary arterial hypertension (PAH)
- Licensed from Eisai Co., Ltd.



IND application submitted (July 2024)

**CG009301** (GSPT1 protein-targeting decomposition drug)

- Indication: Malignant blood tumors (leukemia)
- Third IND application following TRK



# Expanding the business to Australia

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

**Aiming to prompt start clinical trials**

## Partnership with the Governance Partners

1. A partnership enable GNI to invest into cutting edge technologies in Japan
2. Attract global investors including US, Europe and China
3. Forge strategic relationship in the fast-growing Asia Pacific economy

# Further developments in Japan

Partnership with Governance Partners  
**Consolidation of Governance Partners ASIA Fund as a Subsidiary**

**Holding 18.5% in Japan Asia Investment Co., Ltd. shares through ASIA Fund\***

\*Out of the 18.5%, the portion held according to the ASIA Fund's contribution is 17.95%.  
Additionally, our direct holding is 0.5% (as of June 28).

## 4. Financial Forecasts for FY2024

# Financial forecasts for FY2024

Subject to progress of some key events in the 2<sup>nd</sup> half of 2024

(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. Second Half of FY2024 Topics

## **Notable events in the 2<sup>nd</sup> half of 2024**

- 1. Receive results of Phase 3 clinical trial of F351**
- 2. Cullgen's listing as a public company**
- 3. Progress of R&D and clinical trials**
- 4. M&A**
- 5. Progress in preparation for transition to Prime**

## 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



Achieved in Q2 FY2024  
(effective from August 30)

Goal after FY2025: JPX-Nikkei Index 400 Index



## 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**

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

\* Listed on NASDAQ

Madrigal Pharmaceuticals Inc. (a competitor) market cap: 776.1 billion yen

※Based on August 12, 2024 close

**Cullgen**

**7.3 billion yen**

**??? billion yen**

Arvinas, Inc. (a competitor) market cap: 248.9 billion yen

※Based on August 12, 2024 close

**MedTech Group (BAB + BB)**

**8.5 billion yen**

**??? billion yen**

Q2 FY2024

Revenue 2.5 billion yen

Op. Profit 660 million yen

FY2023

Revenue 2.7 billion yen

Op. Profit 1.33 billion yen

# Macro Economy Discussion

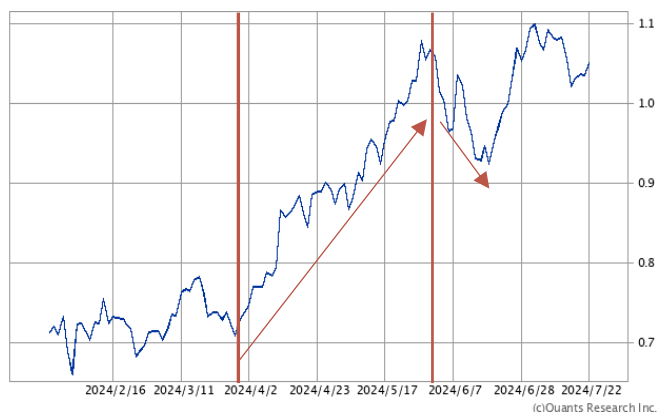
## Macro factors: interest rate trends

- As interest rates began to rise in April, growth stocks were sold in inverse proportion to the market.
- Among these, our company's stock, which has a large liquid market capitalization, was sold.  
→ Japan Securities Dealers Associations' outstanding loan balance increased by approximately 96% between the end of March and the end of July.

GNI Group



10-Year Treasury Yield



Expected Sell Balance

Publication	Loan balance (As of March 29)	Loan balance (As of July 29)	Inc. / (dec.)
JSDA	3,855,141	7,553,965	<b>+ 95.9%</b>

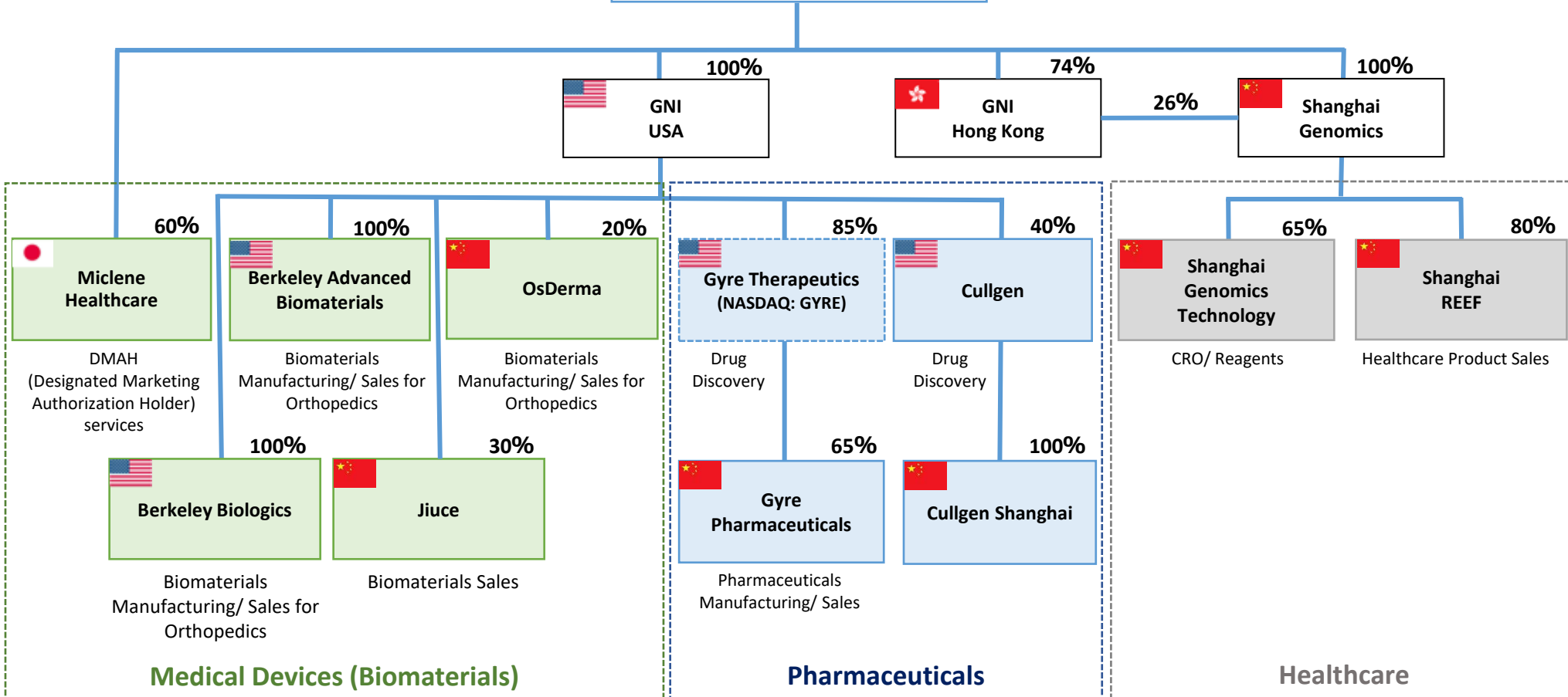
Buy Balance

Publication	Buy balance (As of March 29)	Buy balance (As of July 29)	Inc. / (dec.)
TSE	5,131,500	5,732,700	<b>+ 11.7%</b>

Company	FFW (Free Float Weight)	FF market cap (end of March)	FF market cap (end of July)
<b>GNI Group</b>	<b>81%</b>	<b>126.1 billion yen</b>	<b>93 billion yen</b>
Competitor company A (Prime)	18.2%	33.6 billion yen	65.6 billion yen
Competitor company B (Prime)	10.1%	15 billion yen	15.2 billion yen
Company C (Growth/ Same range of market cap)	18.2%	26.6 billion yen	22.1 billion yen

## 7. Supplementary Materials

# Group structure



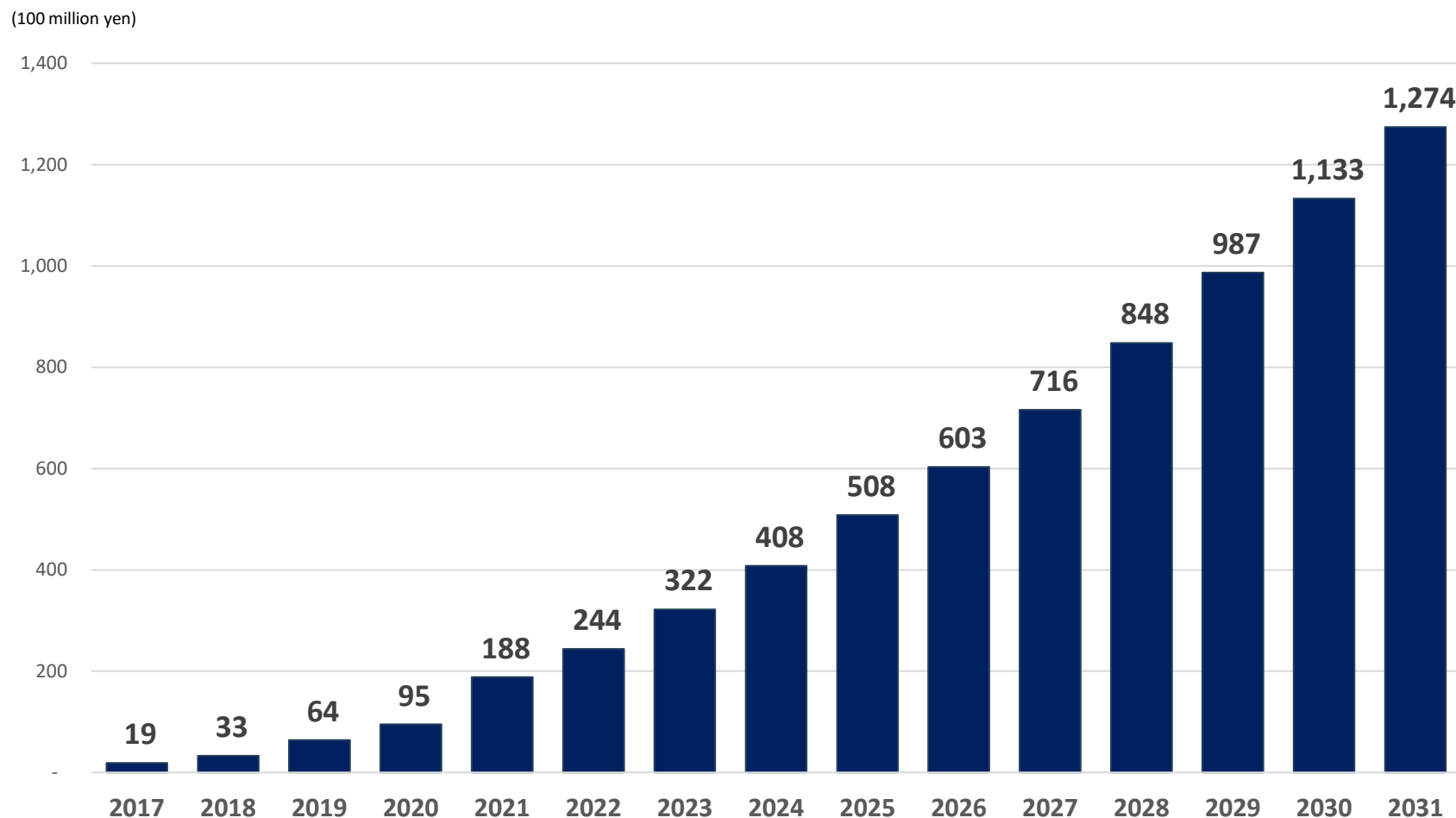
# Development Pipeline of Gyre Therapeutics & Gyre Pharmaceuticals

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]	Received IND approval in May 2024					

# Development pipeline of Cullgen



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



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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