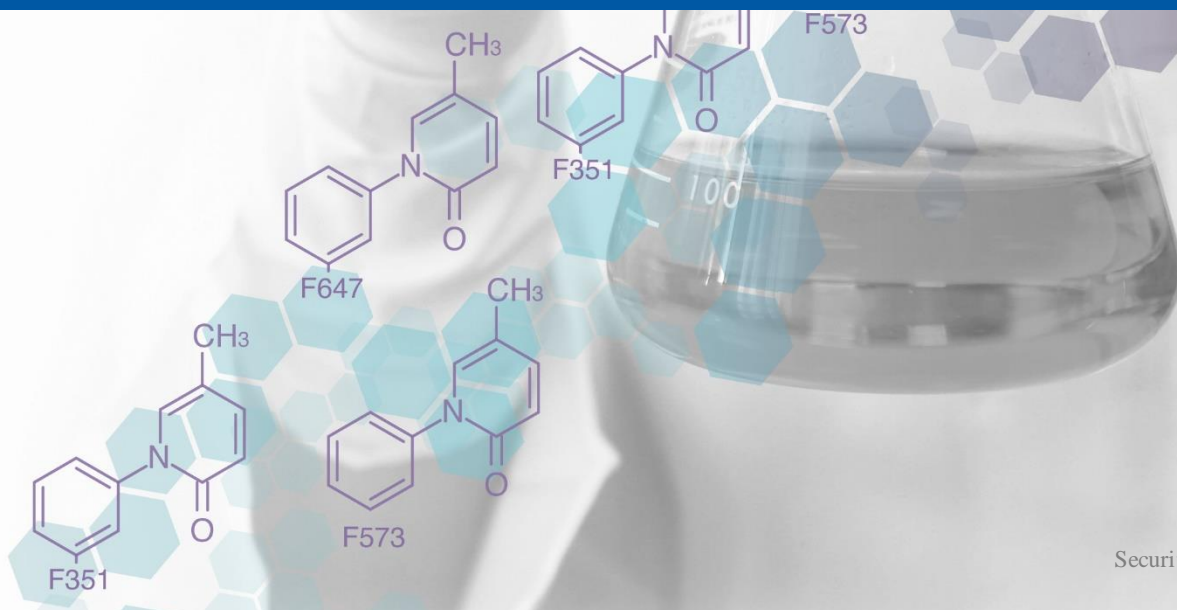




GNI Group Ltd.

Financial Results for FY2023 Q3



**We Bring New  
Hope to Life.**

# Agenda

**1. Company Profile**

**2. Financial Highlights**

**3. Upward Revision of Full-year Forecast**

**4. Topics**

**5. GNI's Value**

**6. Supplementary Material**

# 1. Company Profile

## COMPANY OVERVIEW

### Head Office Address

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

### Main business

Global pharmaceutical R&D, manufacturing and distribution, and bio-materials businesses

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### Incorporation

2001 Nov.

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### President and CEO

Ying Luo Ph.D.

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### Common stock

10,912 Millions of yen (as of the end of September 2023)

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### Number of Employees (Group as a whole)

774 (as of the end of September 2023)

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### Listed on

TSE Growth Market  
(Listed in August 2007/Securities code: 2160)

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### Main bases

Japan, the United States and China

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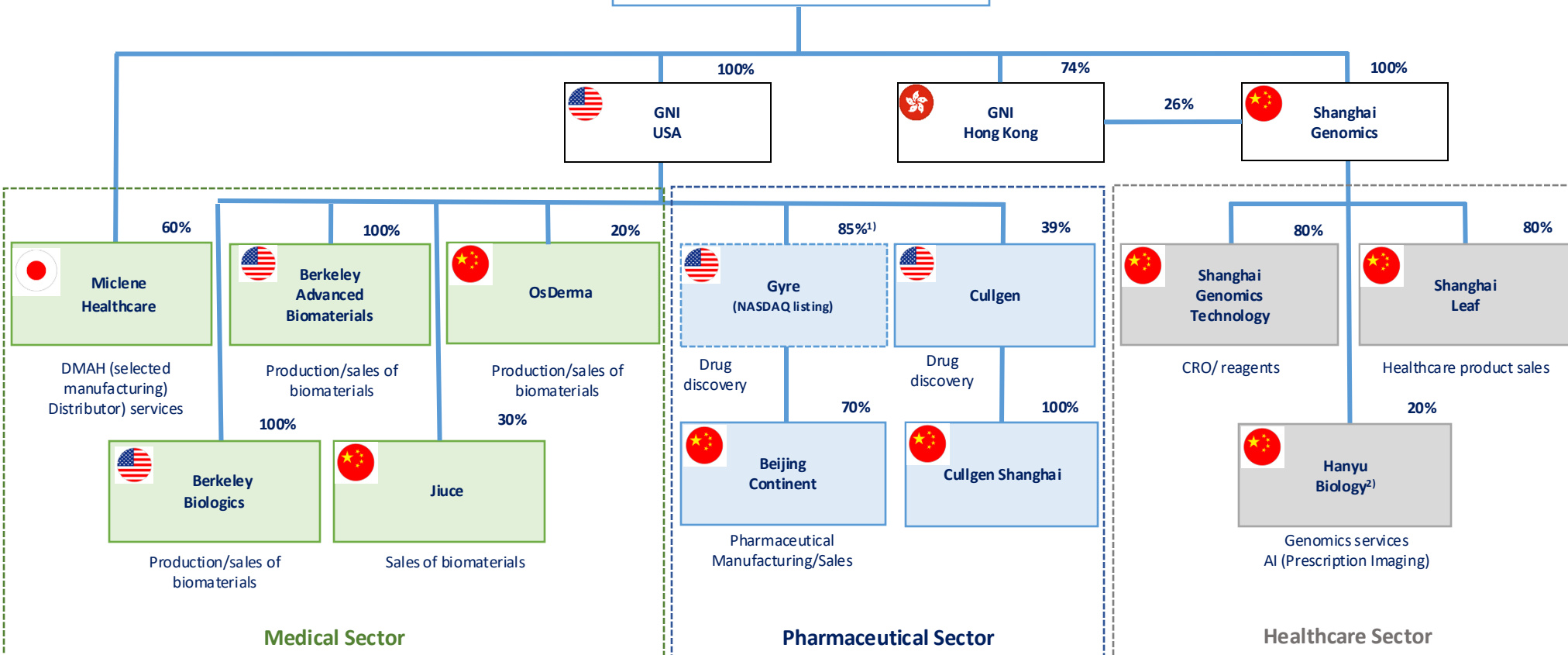


**Director, Representative Executive Officer,  
President and CEO**

**Ying Luo**

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

# Group Structure



1) Our corporate name was changed from CBIO to GYRE on October 31, making us a consolidated subsidiary.

2) Non-application of equity method

# Major subsidiaries

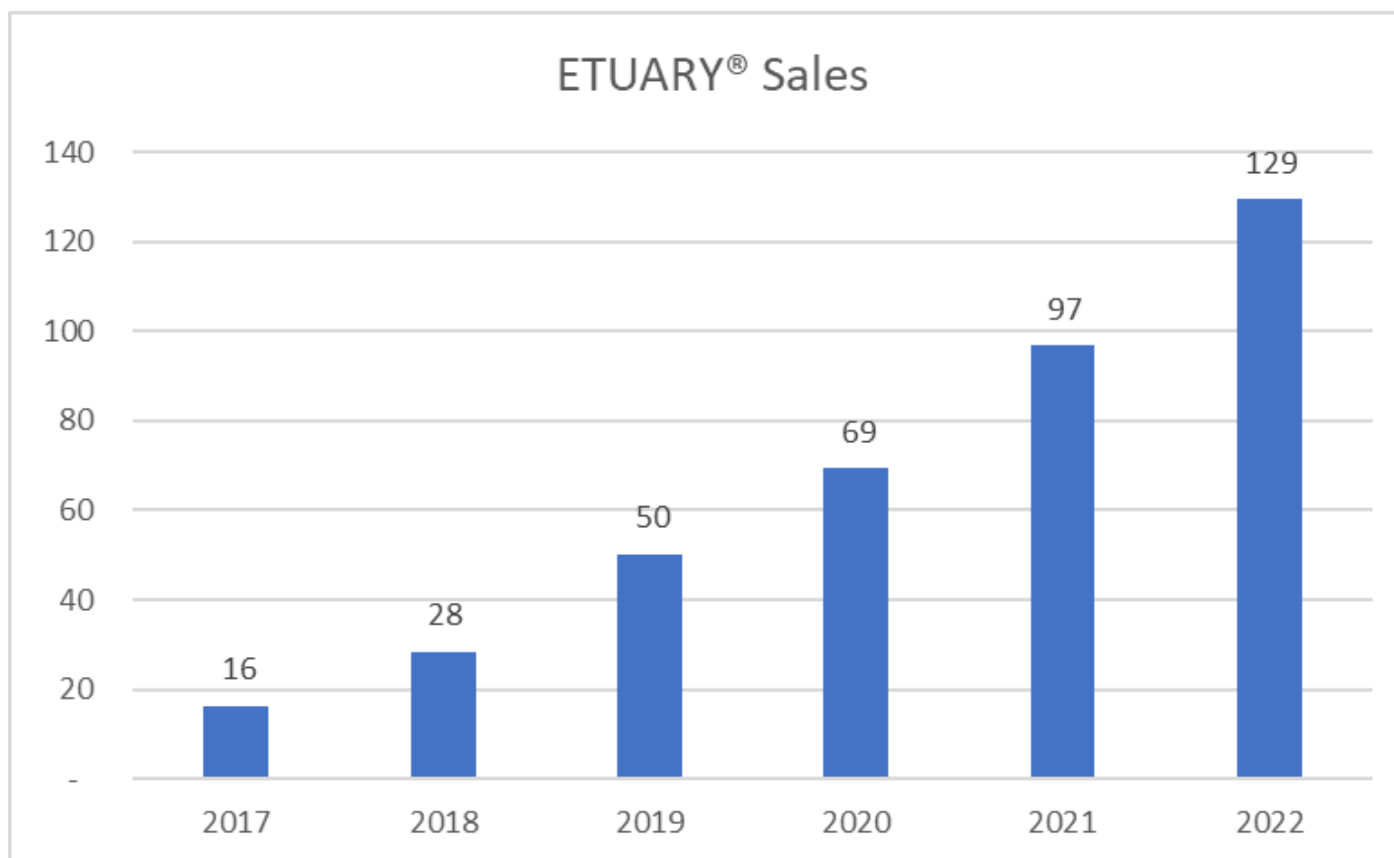
Name	Full Name/Description
<b>BAB</b>	<p><b>Berkeley Advanced Biomaterials LLC</b>            Biomaterial Business Development in the U.S.            (Medical Device Segment)</p>
<b>Gyre</b>	<p><b>Gyre Therapeutics, Inc.</b>            Developing MASH therapeutics            Holds F351's non-Chinese rights</p>
<b>BC</b>	<p><b>Beijing Continent Pharmaceutical Co., Ltd</b>            Drug Discovery and Pharmaceutical Business Development in China            Over 500 MR and build a sales network            Manufacturing and sales of ETUARY®            Developing F351</p>
<b>Cullgen</b>	<p><b>Cullgen Inc. and Cullgen (Shanghai), Inc.</b>            Develop drug discovery business in the U.S. and China            Alliance with Astellas Pharma Inc.            Invested by AstraZeneca</p>



## What is GNI Group (1)

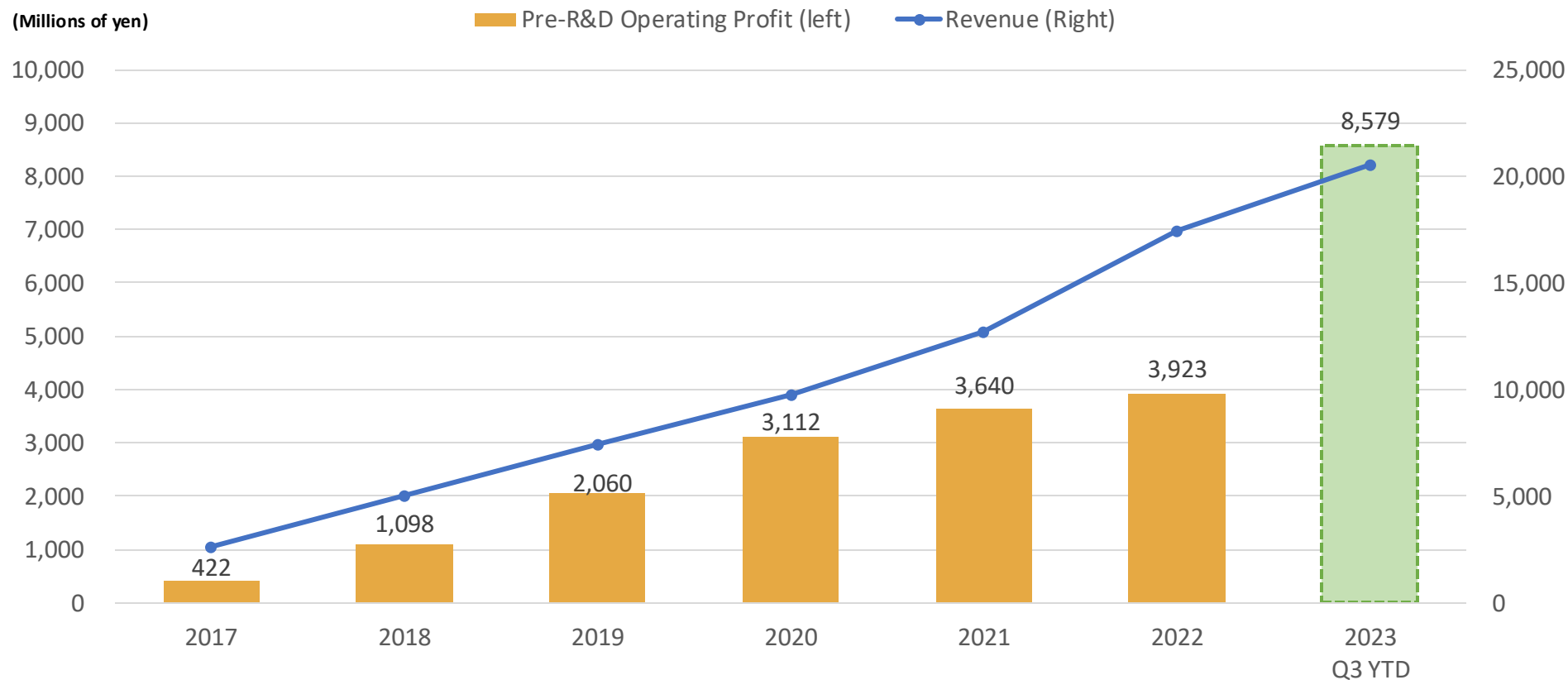
# From Drug Discovery Success to Pharmaceuticals

(100 Million JPY)



## What is GNI Group (2)

# Industry's scarce, profitable companies



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

## What is GNI Group (3)

**High development capabilities recognized worldwide**

**Signed a large-scale contract with Astellas Pharma Inc. totaling ~¥300 billion**  
(Subsidiary Cullgen)

**Investment received from AstraZeneca funds**  
(Subsidiary Cullgen)

## What is GNI Group (4)

**Hold a Nasdaq-listed company**

**Extremely rare among listed Japanese companies**

**To have a Nasdaq-listed company**

**As a subsidiary**

**GNI Group is, in the end, is a Japanese corporate group that**

- ✓ **Operates globally in the USA and China as well as Japan**
- ✓ **Demonstrates world-class development capabilities while succeeding in drug discovery and making profits as a pharmaceutical manufacturer**
- ✓ **Under the vision of “We Bring New Hope for Life”**
- ✓ **Further enhances new drug development efforts and realizes unlimited growth potential**

## 2. Financial Highlights

# Income Statement Summary

Dramatic increases in both sales and profits Record-high sales and profits

Millions of yen	2022 3Q YTD	Vs. Revenue	2023 3Q YTD	Vs. Revenue	Increase Rate
<b>Revenue</b>	12,761	100.0%	20,547	100.0%	61.0%
<b>Gross profit</b>	10,853	85.1%	18,178	88.5%	67.5%
SG&A	7,498	58.8%	9,556	46.5%	27.4%
R&D	1,819	14.3%	1,776	8.6%	△2.3%
<b>Operating income</b>	1,494	11.7%	6,802	33.1%	355.3%
<b>Quarterly profit before tax</b>	1,223	9.6%	6,376	31.0%	421.3%
<b>Quarterly profit</b>	324	2.5%	4,804	23.4%	1381.0%
<b>Quarterly profit attributable to parent company</b>	1,076	8.4%	2,213	10.8%	105.7%

# Balance Sheet Highlights

Substantial increase in liquidity on hand

Millions of yen	2020 End	2021 End	2022 End	2023 3Q	Increase Rate
Total non-current assets	10,194	12,109	16,759	21,766	29.9%
<b>Total current assets</b>	<b>13,024</b>	<b>18,187</b>	<b>17,147</b>	<b>26,701</b>	<b>55.7%</b>
<b>Total assets</b>	<b>23,219</b>	<b>30,296</b>	<b>33,906</b>	<b>48,468</b>	<b>42.9%</b>
Total non-current liabilities	3,846	8,487	10,592	16,895	59.5%
Total current liabilities	6,603	2,543	3,503	4,986	42.3%
<b>Total liabilities</b>	<b>10,450</b>	<b>11,030</b>	<b>14,096</b>	<b>21,881</b>	<b>55.2%</b>
Capital and other	11,859	17,108	17,125	16,402	△4.2%
Retained earnings	△ 608	307	696	2,909	317.8%
Other components of equity	△ 251	1,444	3,147	4,907	55.9%
Equity attributable to parent company	11,000	18,860	20,969	24,220	15.5%
Non-controlling interests	1,769	405	△ 1,158	2,366	-
<b>Total shareholders' equity</b>	<b>12,769</b>	<b>19,266</b>	<b>19,810</b>	<b>26,586</b>	<b>34.2%</b>



## Ample Cash

**Cash 21.3 billion yen**

**Current assets**

**26.7 billion yen**

**Cash and cash equivalents**

**18.14 billion yen**

**Other financial assets (long-term deposits)**

**3.16 billion yen**

# R&D Expenses

(Millions of yen)

	FY2020 Full year	FY2021 Full year	FY2022 Full year	FY2023 Q3 YTD
Consolidated R&D costs	1,243	2,015	2,545	1,776
Capitalized development costs	60	336	606	655
<b>Total</b>	<b>1,303</b>	<b>2,351</b>	<b>3,151</b>	<b>2,431</b>

## 3. Upward Revision of Full-year Forecast

# Upward Revision of Full-year Results

- ① **Strong revenue** from ETUARY®
- ② **Stable monthly revenue** based on a large-scale contract with Astellas Pharma Inc.

Millions of yen	Previous Forecast (A)	Actual figures (B)	Change (B-A)	Rate of change (%)	(Reference) Previous year (FY2022)
Revenue	25,273	26,267	994	3.9%	17,418
Operating income	5,991	7,280	1,289	21.5%	1,377
Profit before tax	4,143	6,430	2,287	55.2%	767
Profit after tax	2,174	4,351	2,177	100.1%	(868)
Owner's Profit	1,703	2,005	302	17.7%	388
Basic EPS (Yen)	35.86	42.20	-	-	8.19

Revised Forecast Use Exchange Rate: US\$1 = ¥138.24 / RMB 1 = ¥19.62

## Topic (1)

**Strong sales of ETUARY®****① Revenue size**

Q3 2022 YTD

9.7 billion yen

(Q2 YTD: ¥6.3 billion)



Q3 2023 YTD

11.7 billion yen

(Q2 YTD: ¥7.3 billion)

**② Further expansion**

= In order to meet various needs,

**Active clinical trials to expand indications**

## Topic (2)

**Signing a large-scale contract with Astellas Pharma Inc.**

**In addition to one-time income**

**Monthly stable earnings are generated**

## 4. Topics

## Topic (1)

# Birth of Gyre



## Topic (1) Description

**GNI Group**



A subsidiary with 85.2% ownership\*

**Gyre Therapeutics, Inc.(GYRE)**



A subsidiary 69.7% ownership

**Beijing Continent (BC)**

\*After conversion of preferred stock

## Topic (1) Description

**October 31, 2023**

**Gyre listed on NASDAQ**

**\*Newly listed by taking over CBIO**

## Topic (1) Significance

- **Accelerate Global Growth**
- **Groundwork for becoming a global mid-tier pharmaceutical company**  
= **Acquiring of global valuations**

## Topic (2) Drug Discovery Progress

# Completed F351 Ph3 enrollment

**Over 2 months ahead of schedule**

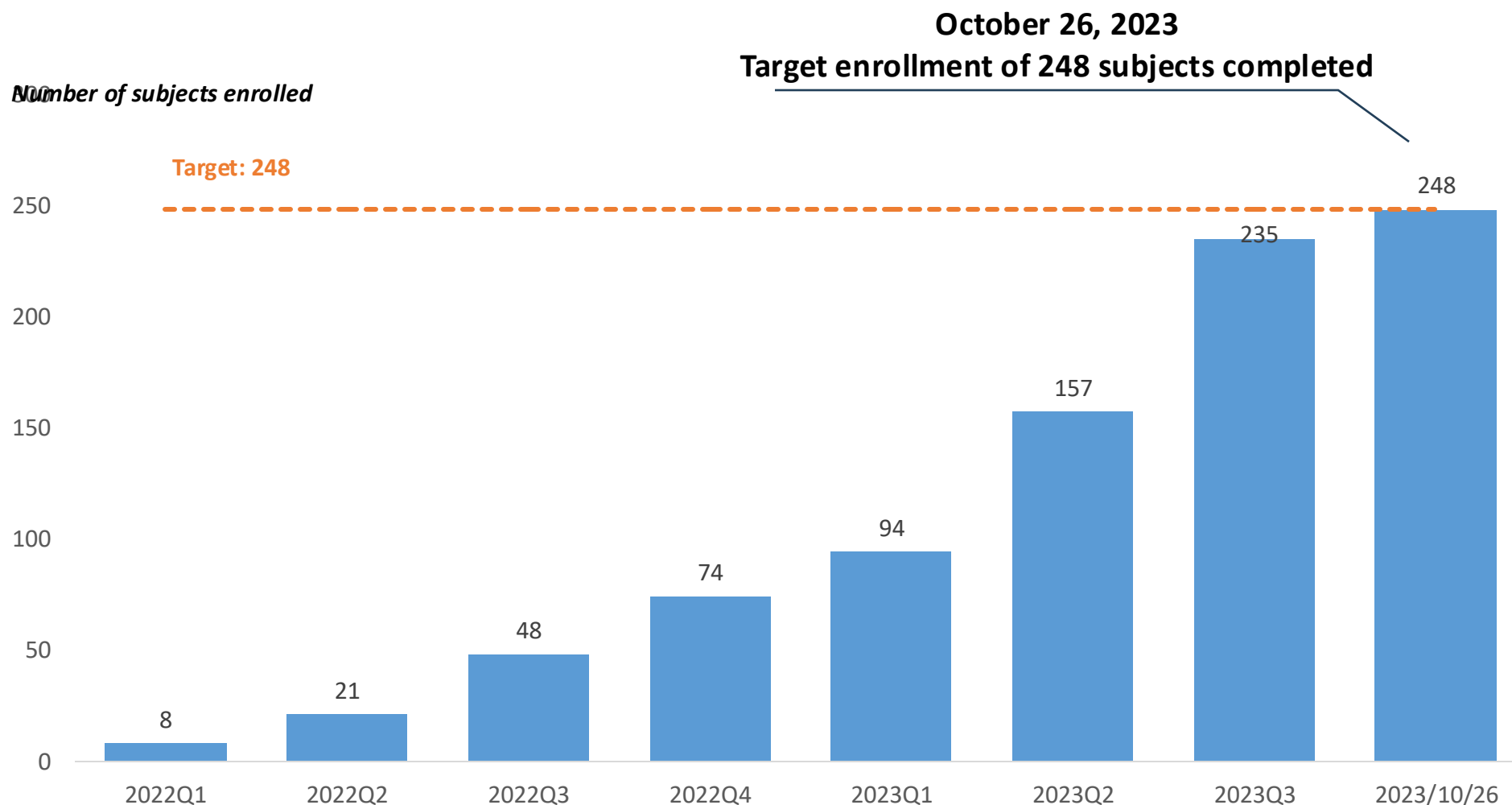
**Achieved in October**

**2024 data announced**

**→ Aim to launch early**

F351 is a promising therapeutic drug candidate which BC is developing for pulmonary fibrosis for which an approved drug still does not exist. If the clinical trial is successful, the compound that could become a blockbuster drug. It was designated as a breakthrough therapeutic drug by China NMPA (National Medical Products Administration) in 2021.

# F351 Phase III Clinical Trial Enrollment Progress



## Topic (2) Future Developments

**BC** - **F351 in China**  
**Expansion of Ice Revue Application**

**Gyre** - **Non-Chinese F351**  
**MASH in the USA\***  
**Phase II trial to be initiated**

**Toward global expansion**

**\*Previously known as Nonalcoholic steatohepatitis (NASH)**  
**→Metabolic Associated Steatohepatitis**

## Topic (3) Biomaterials Business M&A

**A Nasdaq-listed company Elutia  
Acquisition of orthobiologics business**



**Biomaterials business  
Increase revenue to ¥5 billion for the next fiscal year**



**To increase stable earnings**

## Topic (4) Increasing market capitalization

# Partial revision of corporate valuation

## Increasing Market capitalization



Moving up to **Tokyo Stock Exchange Prime Market** in sight



## 5. GNI Group's Value

# Point: Book Value versus Market Value

	<u>Book value</u>	<u>Current Value</u>
<p><b>Gyre (incl. BC)</b> *Listed on Nasdaq</p>	<p><b>400 million yen</b></p>	<p><b>251.7 billion yen</b> <b>(GNI owned portion)</b> <small>※ Based on November 30, 2023 close</small></p>
<p><b>Cullgen</b> *Arvinas (a comparable) market cap: more than ¥130 billion</p>	<p><b>8.8 billion yen</b></p>	<p><b>???? billion yen</b></p>
<p><b>BAB</b> *2022 2023Q3</p>	<p><b>6.4 billion yen</b> Revenue 2.4 billion yen Revenue 2.1 billion yen</p>	<p><b>??? billion yen</b> Op. Profit 1.19 billion yen Op. Profit 1.05 billion yen</p>

## Point: GNI Group's Value

**GNI market capitalization 160.6 billion yen**

※ Based on November 30, 2023 close

<b>Net cash</b>	<b>20.0 billion yen</b>
<b>Gyre (GNI-owned portion)</b>	<b>251.7 billion yen</b>
<b>Cullgen</b>	<b>???? billion yen</b>
<b>BAB</b>	<b>???? billion yen</b>

**What is the fair market capitalization?**

## Point: Market value-based PBR

### GNI market capitalization of ¥160.6 billion

Book Value Basis (BS)			Market value basis	
Assets 48.4 billion yen	Liabilities 21.8 billion yen		Fair value assets* 299.7 billion yen + ???	Liabilities 21.8 billion yen
	Net assets 24.2 billion yen Non-controlling interests 2.3 billion yen			Net assets at market value 275.6 billion yen Non-controlling interests 2.3 billion yen + ???

\*GNI's total assets plus the increase in Gyre's value which GNI holds

Market-value based PBR: below  $1606/2756=0.58$

**= Well below 1**

※ Based on the closing price of November 8, 2023

Point: Growth + Value

**GNI Group is the corporate group which**

**Maintains high growth (growth stock)**

**but also**

**Possesses ample assets and has a facet of  
an under-valued stock (value stock)**

## Point: Warrants Removed

**46<sup>th</sup> and 47<sup>th</sup> = All exercised**


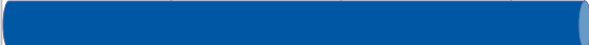





**48<sup>th</sup> = All bought back  
All cancelled**

**Remaining warrants for institutional investors =>  
None**

**Resolved future dilution concerns**

## 6. Supplementary Material

# BC's Development Pipeline

		Beijing Continent pharmaceutical co. ltd 					
Product		Indication	Preclinical	Phase I	Phase II	Phase III	NDA
Pulmonary Diseases	Fibrosis-associated	ETUARY® (Pirfenidone)	Dermatomyositis Interstitial Lung disease (DM-ILD) ★				
			Systemic Sclerosis-associated Interstitial Lung Disease (SSc -ILD) ★				
			Pneumoconiosis				
	Others	F528	Chronic Obstructive Pulmonary Disease (COPD)				
		F230	Pulmonary Arterial Hypertension (PAH) ★				
Liver Diseases	Fibrosis	F351 (Hydronidone)	Chronic Hepatitis B pulmonary Fibrosis				
	Other	F573	Acute Liver Failure (ALF) / Acute-on-Chronic Liver Failure (ACLF) ★				
Kidney Disease	Fibrosis Related	ETUARY® (Pirfenidone)	Diabetic Kidney Disease (DKD)				

★ Rare Disease

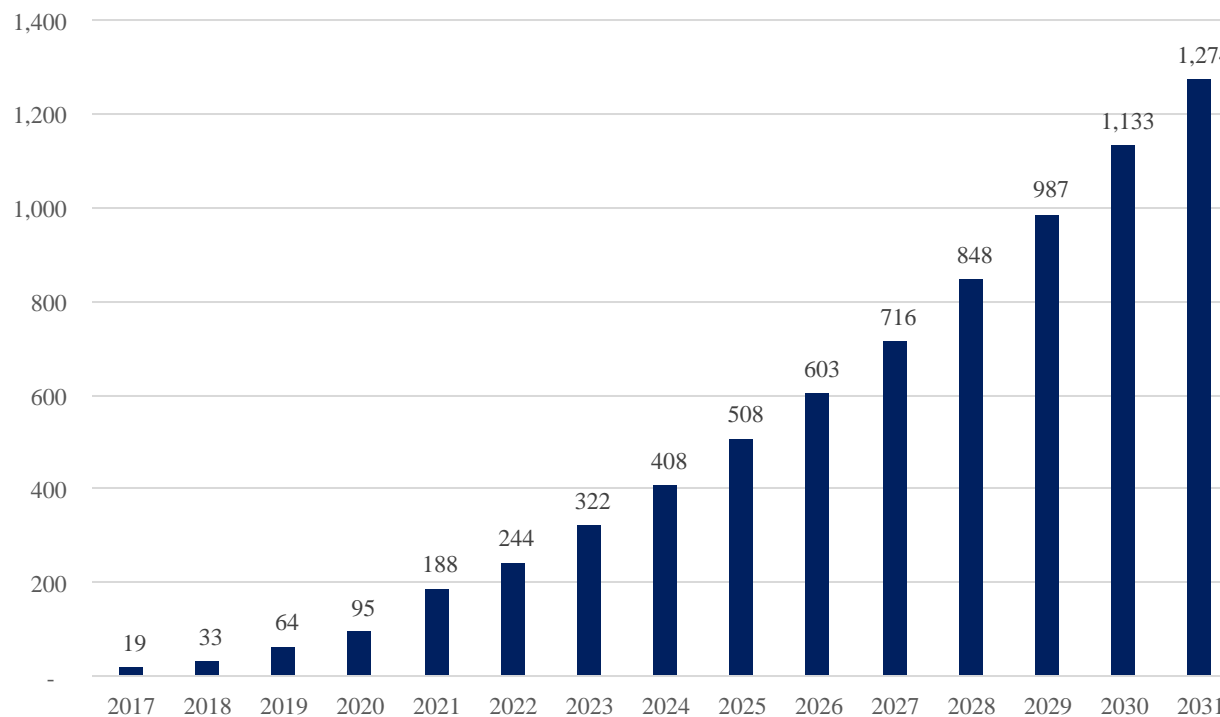


# Cullgen's Development Pipeline

cullgen						
Target Area	Indication	preclinical	Phase I	Phase II	Phase III	NDA
Cell cycle (a)	Breast, pancreatic, lung cancer, malignant melanoma, novel immunotherapeutics					
Cell cycle (b)	Breast and ovarian cancer					
Epigenetics	Prostate and bladder cancer					
Metabolism	Novel Immunotherapeutics					
Tropomyosin Receptor Kinase (TRK)	Solid cancer and pain					
DNA repair	Colon ovarian cancer and gastrointestinal cancer					
Translation	Colon Ovarian Gastrointestinal Cancer					
Transcription	Diffuse large B-cell lymphoma, Triple negative breast cancer					

# Market Size of ETUARY®: Pulmonary Fibrosis Drugs Market in China

(100 Million JPY)

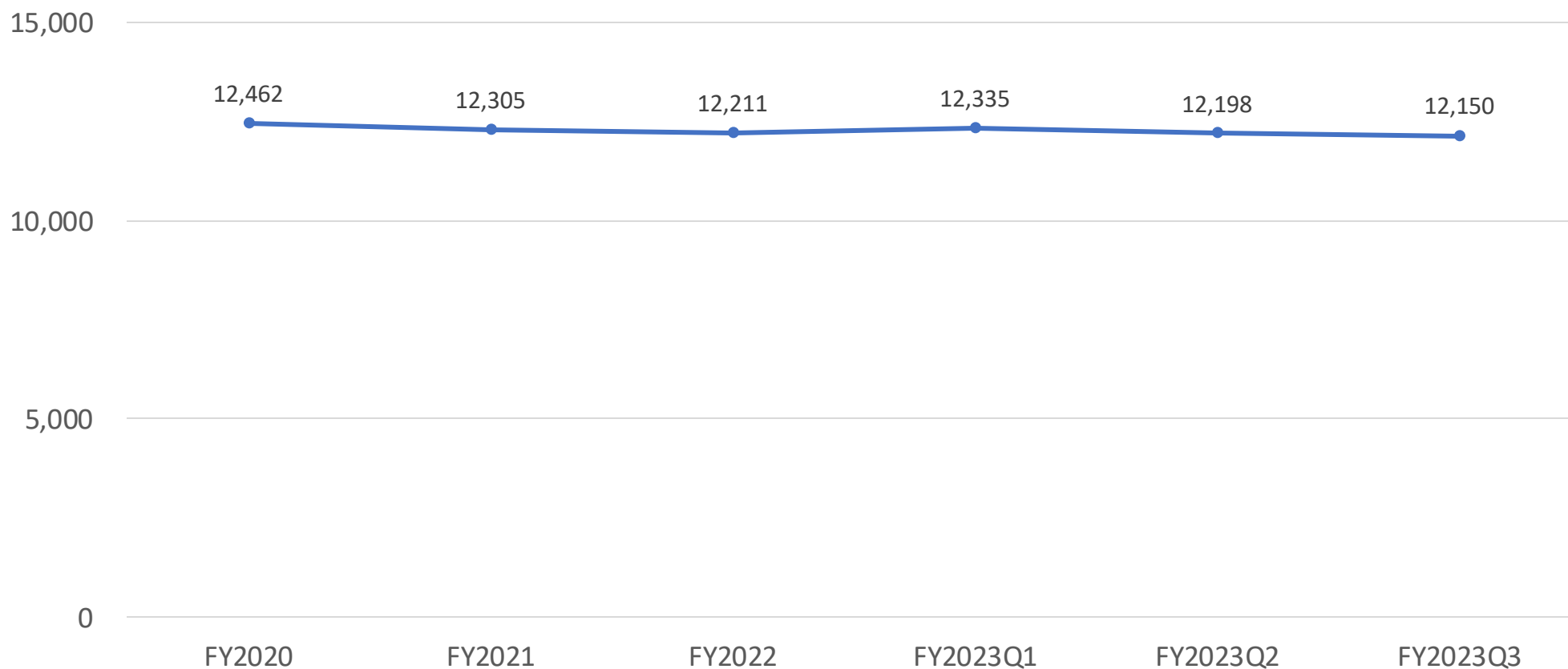


Source: Frost & Sullivan (converted to yen by GNI)

## ETUARY® Unit Price Trends

(Unit: yen)

### ETUARY® Average Price per Bottle



# F351 Phase II 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:	
	-14.89 (-33.32,4.99)		-30.52 (-48.12,-9.50)	
	PPS:		PPS:	
	-21.03 (-40.20,0.26)		-39.52 (-56.83,-17.26)	
			PPS: -26.75 (-45.78,-4.75)	

Source: GNI disclosure on Oct. 23, 2023

## F351 Phase II Top-line Data Overview (2/3)

### Efficacy Results:

additional analysts for patients with Ishak score = 6 (cirrhosis stage)

Efficacy Analyses	Placebo	F351 (all groups)
Ishak score down by 1+ As of 52nd week (FAS)	1 (1/4, 25%)	12 (12/15,80%)
Ishak score down by 1+ As of 52nd week (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 disclosure on Oct. 23, 2023

## F351 Phase II 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/day 3 doses/day group: 2.38%**
  - **F351 : 90mg/day 3 doses/day group: 2.38%**
  - **F351 : 120mg /day 3 doses/day group: 7.32%**
  
- ✓ **No fatalities in the trial**

Source: GNI disclosure on Oct. 23, 2023

# Contact Info:

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### Investor Relations

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

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