



GNI Group Ltd.

# FY2023 Full Year Financial Results Corporate Presentation

**We Bring New  
Hope to Life.**



# Agenda

- 1. Company Profile**

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- 2. Financial Highlights**

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- 3. 2023 Topics**

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- 4. 2024 Fiscal Year Guidance**

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- 5. 2024 Topics**

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- 6. GNI Group's Hidden Value**

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- 7. Supplementary Materials**

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# 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

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### Incorporation

2001 November

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### Paid Capital

13,052 Millions of yen (as of 2023 end)

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### Listing

TSE Growth Market  
Listed in August 2007  
Security code: 2160

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### Main business

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

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### President and CEO

Ying Luo Ph.D.

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### Number of Employees (group-wide)

843 (as of December 31, 2023)

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### Main Locations

Japan, the Americas 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 US 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.

# Major subsidiaries

| 分野         | 会社名  | 事業内容   |
|------------|--|--|
| Pharmatech | <br><b>Gyre Therapeutics, Inc. (GYRE)</b>                 | <b>Nasdaq listed</b><br>Developing MASH therapeutics<br>Holds F351's non-Chinese rights  |
|            | <br><b>Beijing Continent Pharmaceutical Co., Ltd (BC)</b> | Drug Discovery and Pharmaceutical Business Development in China<br>Have over 500 MR and build a sales network<br>Manufacturing and sales of ETUARY®<br>Developing F351   |
| Biotech    | <br><b>Cullgen Inc. (Cullgen)</b>                         | Targeted Protein Degradator Drug Discovery<br>Company with locations in the U.S. and China<br>Collaboration, Option and License Agreement with Astellas Pharma Inc.<br>Recent investment by AstraZeneca CICC<br><b>Preparing for listing opportunities</b> |
| Medtech    | <br><b>Berkeley Advanced Biomaterials LLC (BAB)</b>      | Develop biomaterials business in the U.S. and China<br><b>Aiming for growth and listing in the future</b>  |
|            | <br><b>Berkeley Biologics LLC (BB)</b>                  |  |

# Major Drug Discovery · Pharmaceutical

## <Pharmaceutical>

**Etuary** (Commercial Name : Pirfenidone)



- Chinese : 艾思瑞、 English : ETUARY®
- Treatment for idiopathic pulmonary fibrosis (IPF), **Dominant market share in China**
- Clinical development underway for expansion of indications (Phase 3 trials)

## <Drug Discovery>

**F351** (Commercial name : Hydronidone)



• A promising candidate treatment for liver fibrosis with no existing therapeutic drugs (**Phase 3 trial enrollment completed in China**)

- A potential blockbuster drug if clinical trials succeed
- Recognized as a '**Breakthrough Therapy**' in 2021 by the China National Medical Products Administration
- Indicated for B-type hepatitis in China and MASH\* in the United States



## Targeted Protein Degradator

- Utilizing a proprietary targeted protein degradation technology platform, uSUMITE(TM)
- Aiming to develop small-molecule drugs targeting cancer, pain and autoimmune diseases
- Received investment and appointed directors and advisors from AstraZeneca
- Signed a large-scale contract with Astellas Pharma

\*Metabolic Dysfunction-Associated Steatohepatitis

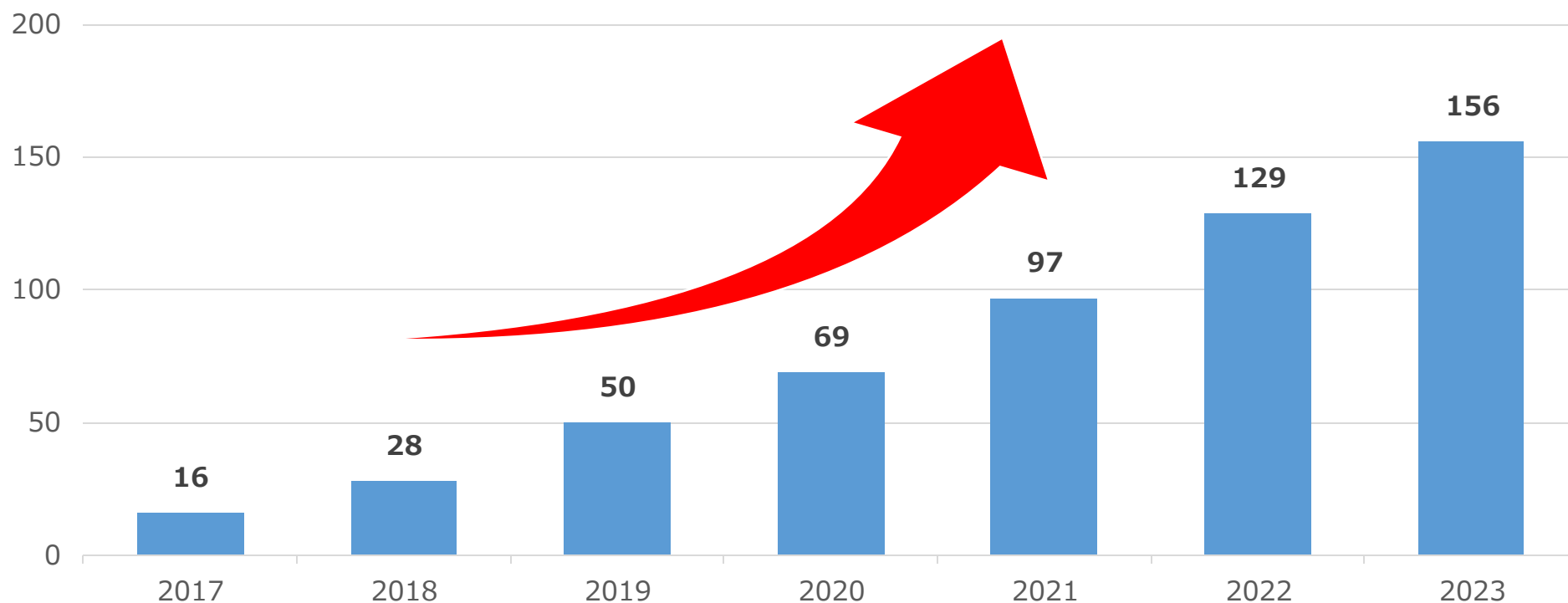


## What is GNI ①

# From Drug Discovery Success to Pharmaceuticals

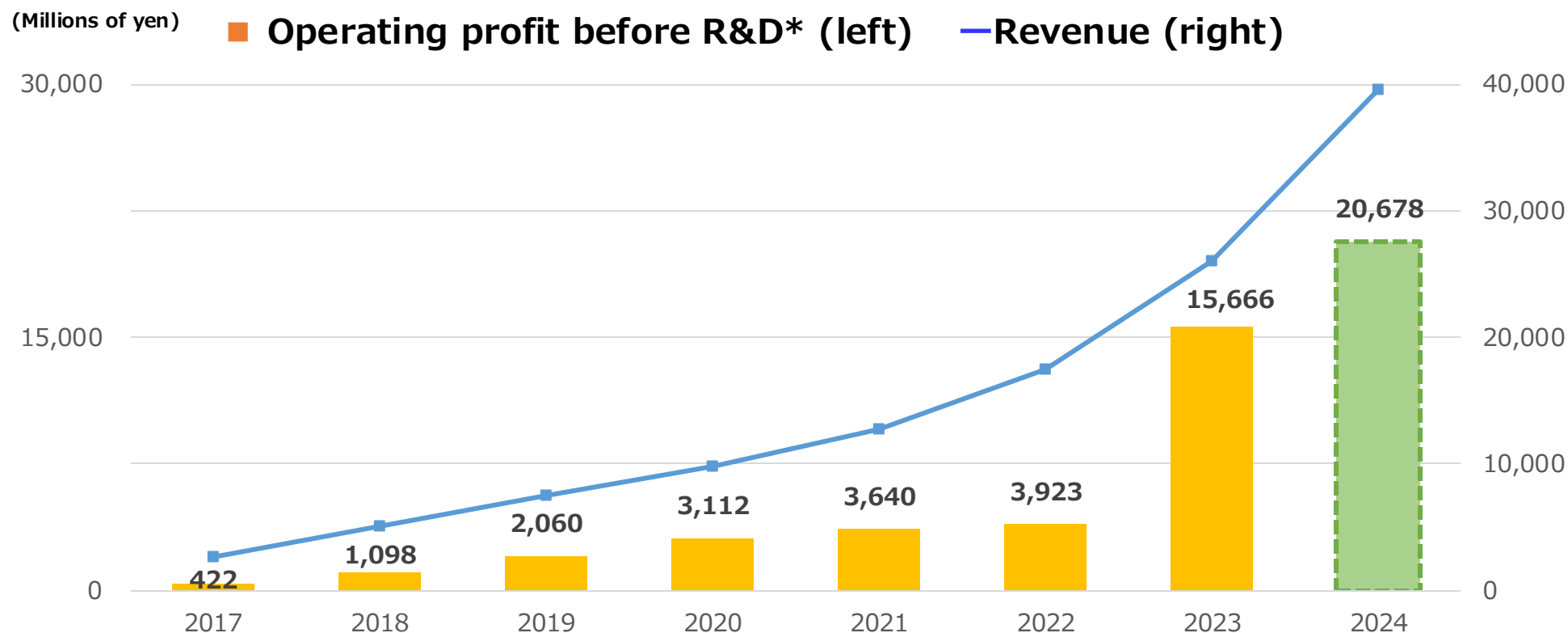
(Unit: 100 million yen)

## ETUARY® Sales



## What is GNI ②

# A Rare, Profitable Drug Discovery Company



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

## What is GNI ③

**High development capabilities recognized worldwide**

**Successful Development** of Commercialization of Etuary

**Satisfactory Safety Profile** for F351

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

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

\*Phase 2 trial results detailed in supplementary materials

**Hold a Nasdaq-listed company**

**Extremely rare among listed Japanese companies**

**To have a Nasdaq-listed company**

**As a subsidiary**

**\*GYRE**

**GNI Group is, in the end, is a 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 to Life”**

**Further enhances new drug development efforts and realizes  
unlimited growth potential**

In other words

## GNI Group

Maintains strong growth (**growth stock**)

but also

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

## 2. Financial Highlights

# Income Statement Summary

## Record-high sales and profits

| Millions of yen                                    | 2022 Full year<br>Cumulative total | Vs. revenue   | 2023 Full year<br>Cumulative total | Vs. revenue   | YoY Change      |
|--|------------------------------------|---------------|------------------------------------|---------------|-----------------|
| <b>Revenue</b>                                     | <b>17,418</b>                      | <b>100.0%</b> | <b>26,010</b>                      | <b>100.0%</b> | <b>49.3%</b>    |
| <b>Gross profit</b>                                | <b>14,744</b>                      | <b>84.6%</b>  | <b>22,431</b>                      | <b>86.24%</b> | <b>52.1%</b>    |
| Selling, general and<br>administrative expenses    | 10,965                             | 62.9%         | 15,292                             | 58.8%         | 39.5%           |
| R&D  | 2,545                              | 14.0%         | 2,557                              | 9.8%          | 0.50%           |
| <b>Operating profit</b>                            | <b>1,377</b>                       | <b>7.9%</b>   | <b>13,108</b>                      | <b>50.0%</b>  | <b>851.3%</b>   |
| <b>Income before income taxes</b>                  | <b>767</b>                         | <b>4.4%</b>   | <b>12,612</b>                      | <b>48.4%</b>  | <b>1,542.5%</b> |
| <b>Net income</b>                                  | <b>△868</b>                        | <b>△4.9%</b>  | <b>9,504</b>                       | <b>36.5%</b>  | <b>-</b>        |
| <b>Profit attributable to owners of<br/>parent</b> | <b>388</b>                         | <b>2.2%</b>   | <b>8,094</b>                       | <b>31.1%</b>  | <b>1,981.1%</b> |



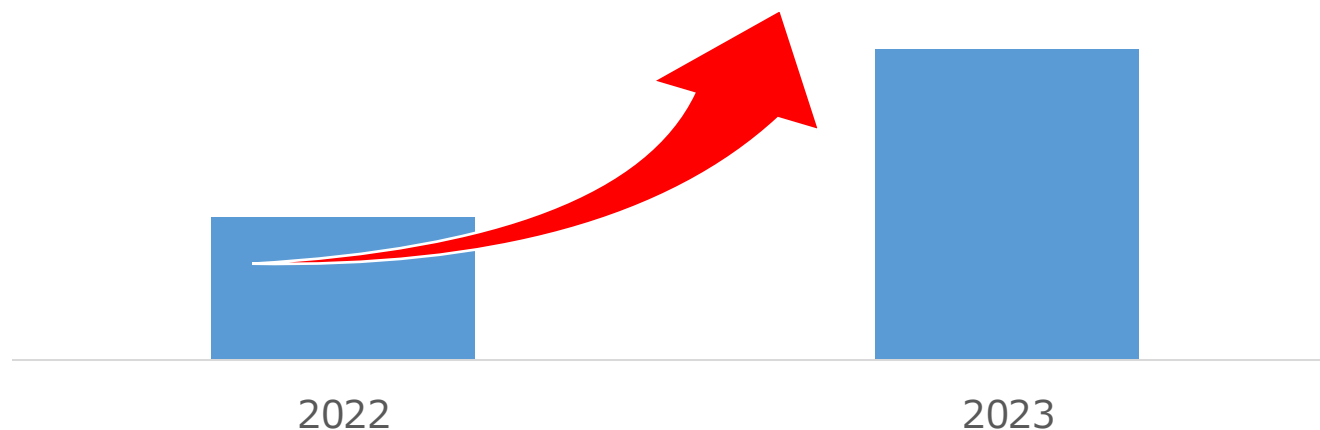
# Balance sheet highlights

## Large increase in liquidity and shareholders' equity

| Millions of yen                      | 2020 End      | 2021 End      | 2022 End      | 2023 End      | YoY Change      |
|--------------------------------------|---------------|---------------|---------------|---------------|-----------------|
| Total non-current assets             | 10,194        | 12,109        | 16,759        | 31,487        | 87.8%           |
| <b>Total current assets</b>          | <b>13,024</b> | <b>18,187</b> | <b>17,147</b> | <b>30,907</b> | <b>80.2%</b>    |
| <b>Total assets</b>                  | <b>23,219</b> | <b>30,296</b> | <b>33,906</b> | <b>62,394</b> | <b>84.0%</b>    |
| Total non-current liabilities        | 3,846         | 8,487         | 10,592        | 18,547        | 75.1%           |
| Total current liabilities            | 6,603         | 2,543         | 3,503         | 7,793         | 122.5%          |
| <b>Total liabilities</b>             | <b>10,450</b> | <b>11,030</b> | <b>14,096</b> | <b>26,341</b> | <b>86.9%</b>    |
| Capital and other                    | 11,859        | 17,108        | 17,125        | 20,431        | 19.3%           |
| <b>Retained earnings</b>             | <b>△ 608</b>  | <b>307</b>    | <b>696</b>    | <b>8,790</b>  | <b>1,162.4%</b> |
| Other components of equity           | △ 251         | 1,444         | 3,147         | 4,569         | 45.2%           |
| <b>Equity attributable to parent</b> | <b>11,000</b> | <b>18,860</b> | <b>20,969</b> | <b>33,792</b> | <b>61.2%</b>    |
| Non-controlling interests            | 1,769         | 405           | △ 1,158       | 2,258         | -               |
| <b>Total shareholders' equity</b>    | <b>12,769</b> | <b>19,266</b> | <b>19,810</b> | <b>36,050</b> | <b>82.0%</b>    |

# Ample Cash

**12.2 billion yen**      **26.4 billion yen**



## Current Assets

|                           |                         |                         |
|---------------------------|-------------------------|-------------------------|
| Cash and cash equivalents | <b>11.0 billion yen</b> | <b>21.6 billion yen</b> |
| Time Deposits             | <b>190 million yen</b>  | <b>1.5 billion yen</b>  |

## Non-Current Assets

|                    |                        |                        |
|--------------------|------------------------|------------------------|
| Long-term Deposits | <b>970 million yen</b> | <b>3.3 billion yen</b> |
|--------------------|------------------------|------------------------|

# R&D

Increasing R&D expenses while increasing profit

(Millions of yen)

|                               | 2020<br>Full year | 2021<br>Full year | 2022<br>Full year | 2023<br>Full year |
|-------------------------------|-------------------|-------------------|-------------------|-------------------|
| Consolidated R&D costs        | 1,243             | 2,015             | 2,545             | 2,557             |
| Capitalized development costs | 60                | 336               | 606               | 940               |
| Total                         | 1,303             | 2,351             | 3,151             | 3,497             |

## 3. 2023 Topics

# Achieved profitability at 3 major subsidiaries

## Pharmatech



- Further sales expansion of ETUARY®

## Biotech



- Ongoing revenues from Astellas Pharma

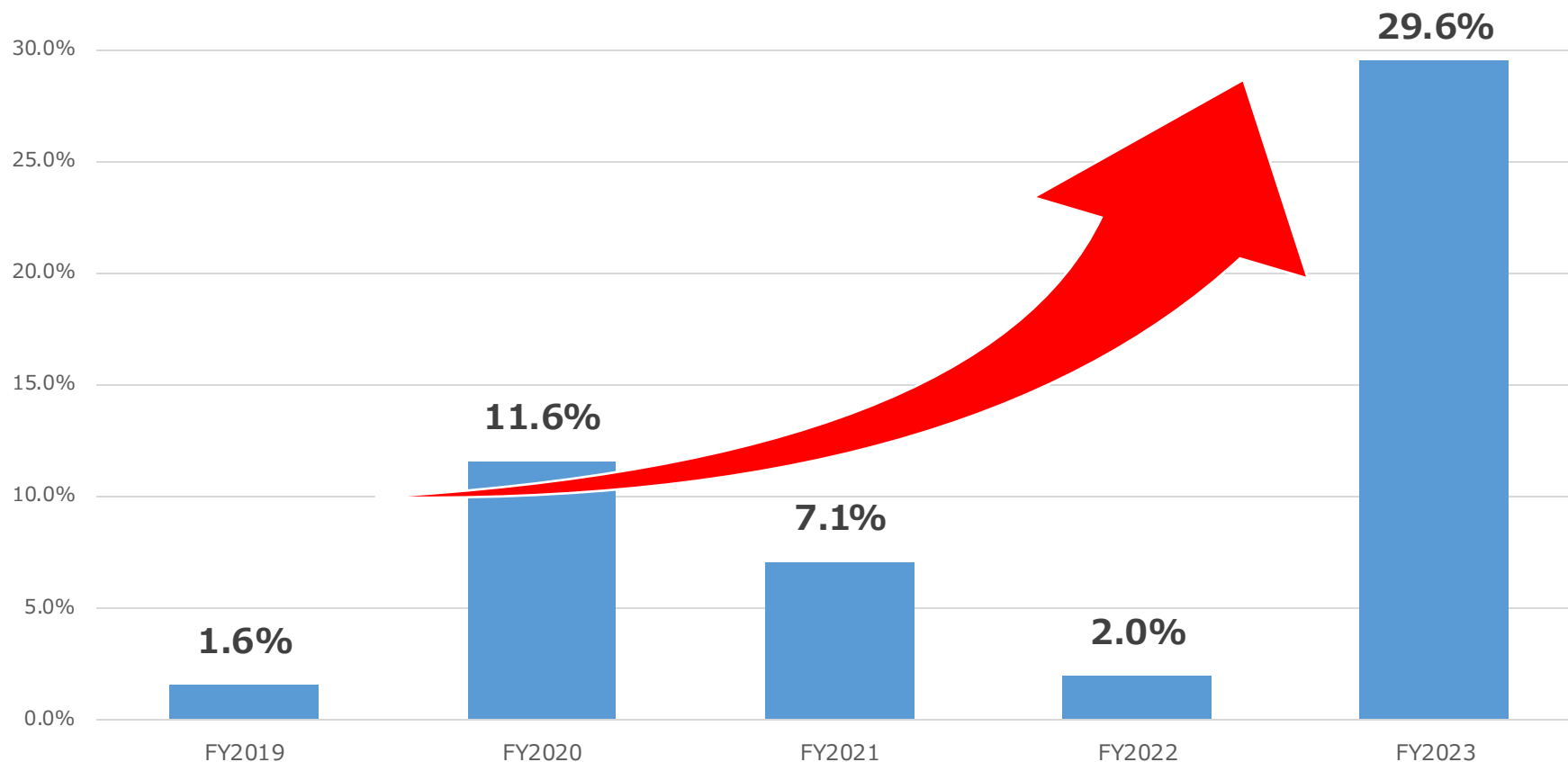
## Medtech



- High profitability
- Stable incomes

# ROE

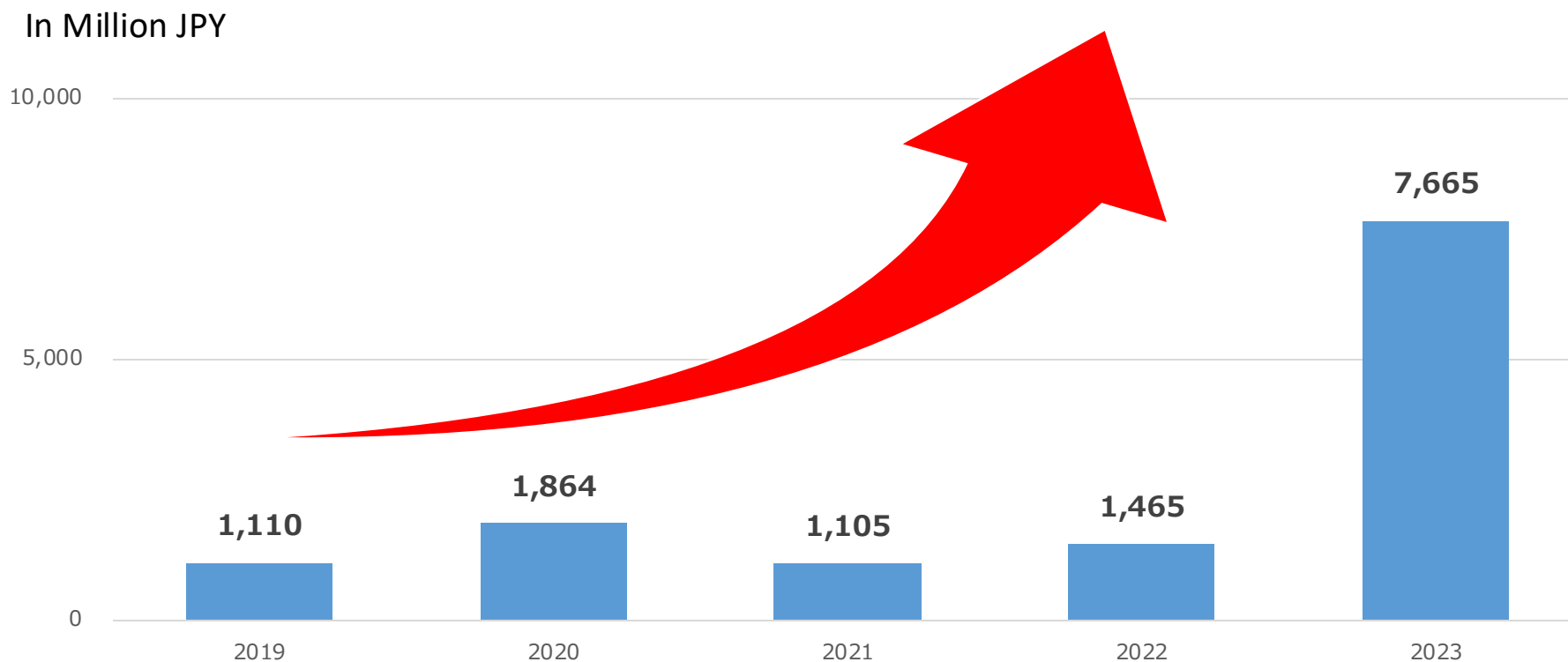
**~30%** Significant growth



\*ROE (Equity Ratio) = Net Income Attributable to Owners of the Parent / Equity Attributable to Owners of the Parent (Average between the beginning and the end of the relevant cumulative period)

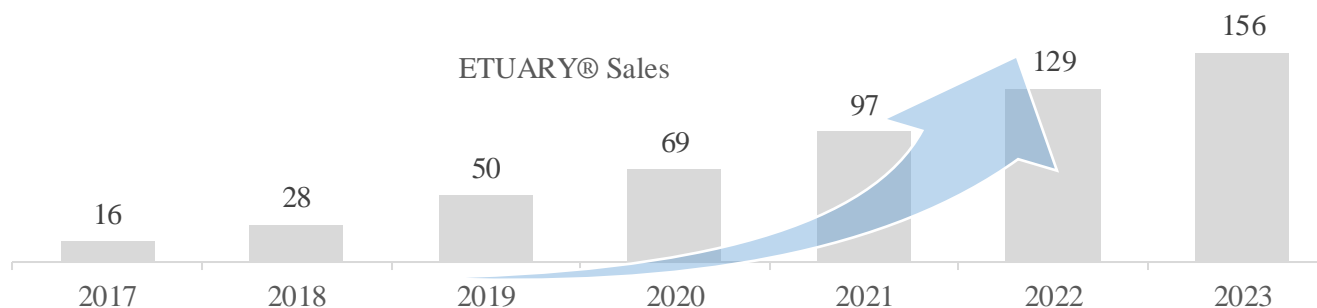
# EBITDA

## Significant Increase



EBITDA=Operation Cash Flow + Tax + Interest Paid – Interest Received

(Unit: 100 million yen) **Strong ETUARY® sales**



**For further expansion**

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**In order to meet various needs,  
Drive more clinical trials to expand indications**



# Birth of Gyre Listed on Nasdaq (As of October 31, 2023)

**Groundwork for GNI Group to become  
a global mid-sized pharmaceutical company**

||

**Acquire global valuations**

# F351

## Phase 3 clinical trial enrollment completed

(October, 2023)

**Over 2 months ahead of original schedule**

2024: Last Patient Out

**→ Aim to launch quickly after approval**

# Partnership with Astellas Pharma

## Joint development with Astellas Pharma

Using proprietary technology, develop multiple pharmaceutical products that degrade proteins causing cancer and other diseases

### In addition to upfront payment,

Generate **stable income** with ability to earn milestone and royalty payments

# Investment from AstraZeneca

2023

**Led by AstraZeneca-CICC Fund, etc.**

2024

**Accept a board director from the AstraZeneca-CICC Fund  
Appoint a scientific advisor from AstraZeneca (U.K.)**

# Acquisition of orthobiologics business



**Increase biomaterials business sales  
to >JPY 5 billion**



**Aim to double the sales in 2 years to generate  
>1/3 of the net profit of the Group**

# Toward the Future

**No** stock acquisition rights remaining for  
investors

**Elimination of concerns about future dilution**

## 4. 2024 Fiscal Year Guidance

# FY2024 Guidance

**Significant revenue and profit increase  
for the 2nd consecutive year**

| Millions of yen                         | In 2023<br>Full-year results | In 2024<br>Full-year guidance | YoY Change |
|---|------------------------------|-------------------------------|------------|
| Revenue                                 | 26,010                       | 39,556                        | 52.1%      |
| Gross profit                            | 22,431                       | 34,264                        | 52.8%      |
| 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. 2024 Topics



## Path to the future

**(1) Preparation for the Prime Market**

**(2) Aim to be selected in JPX indices**

**Goal of 2024: JPX-Nikkei Mid and Small Cap Index**

**Goal of 2025: JPX-Nikkei Index 400 Index**

# Establishing businesses in Japan

Loan repayment from GNI USA



Effective utilization of increased assets



**M&A in Japan**



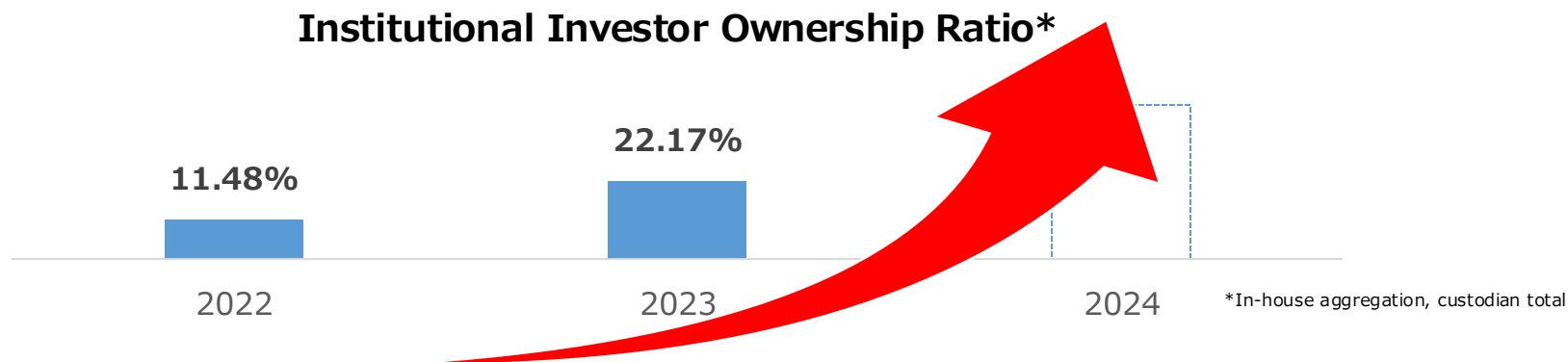
## Groundwork for the future

Aiming to be a **global mid-tier biopharmaceutical company**

Increase in stable shareholders and  
institutional investors

Forward transactions

**5 billion-yen range**



# Revenue Expansion and Global Rollout

(1) Phase 3 **clinical trial for F351** in China

(2) **Indication expansion** of ETUARY®

(3) Planned launch of MASH\* **Phase 2 clinical trial**  
in the United States

\*Formerly known as Non-Alcoholic Fatty Hepatic Infection (NASH)  
→Metabolic Dysfunction Associated Steatohepatitis

Topic ⑤ 2024



(Pharmatech)

# Diversification of Revenue Sources

## Generic Orphan Drugs Strategy in Full Swing

Effective use of existing manufacturing facilities and sales and marketing platform

Supplement the current Orphan drug product - Etuary

Products under development

**Avatrombopag Maleate Tablets**

Indication: Thrombocytopenia due to chronic liver disease

**Fingolimod Hydrochloride Capsules**

Indication: Multiple sclerosis

# 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)

# Joint research with Astellas Pharma ⇒ Steady progress

**Founder of Pioneering Targeted Protein Degradation Technology.  
GNI Group: Providing Investment and Support Since Inception  
Possessing proprietary technology for exploring novel enzymes crucial in  
targeted protein degradation technology**



**Possibility to develop degraders not available in other companies**



# Future Revenue to Reach JPY 10 Billion Range

- ① **Expansion of business** in the United States
- ② **Expansion of product** sales in China
- ③ **Application of biomaterial technology in aesthetics and other fields** in China

## 6. GNI Group's Hidden Value

## Point: Book Value versus Market Value

|   | <u>Book value</u>   | <u>Current Value</u>   |
|---|---|--|
| <p><b>Gyre (incl. BC)</b><br/>*Listed on Nasdaq</p>                                       | <p><b>13.0 billion yen</b></p>  | <p><b>274.1 billion yen</b><br/><b>(GNI owned portion)</b><br/><small>※ Based on February 26, 2024 close</small></p> |
| <p><b>Cullgen</b><br/>*Arvinas (a comparable) market cap: more than 403.6 billion yen</p> | <p><b>4.1 billion yen</b></p>   | <p><b>??? billion yen</b><br/><small>※ Based on February 26, 2024 close</small></p>                                  |
| <p><b>BAB</b><br/>*2022<br/>2023</p>  | <p><b>8.5 billion yen</b><br/>Revenue 2.4 billion yen<br/>Revenue 2.7 billion yen</p> | <p><b>??? billion yen</b><br/>Op. Profit 1.19 billion yen<br/>Op. Profit 1.33 billion yen</p>                        |

## Point: GNI Group's Value

**GNI market capitalization 181.9 billion yen**

**Gyre market capitalization 321.4 billion yen**

※ Based on February 26, 2024 close

**Net cash 23.1 billion yen**

**Gyre (GNI-owned portion) 274.1 billion yen**

**Cullgen ??? billion yen**

**BAB ??? billion yen**

**What is the fair market value?**

## Point: Market value-based PBR

# GNI market capitalization 181.9 billion yen

| Book Value Basis (BS)      |  | Market value basis  |  |
|----------------------------|--|---|--|
| Assets<br>62.3 billion yen | Liabilities 26.3 billion yen   | Market value of assets*<br><b>336.4 billion yen</b><br>+<br>??? | Liabilities 26.3 billion yen   |
|                            | Net assets<br>33.7 billion yen<br>Non-controlling interests<br>2.2 billion yen |   | Net assets at market value<br><b>307.9 billion yen</b><br>Non-controlling interests<br>2.2 billion yen<br>+<br>??? |

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

Market-value based PBR: below  $1,819/3,079=0.6$

**= Well below 1**

※ Based on February 26, 2024 close

Point: Growth + Value

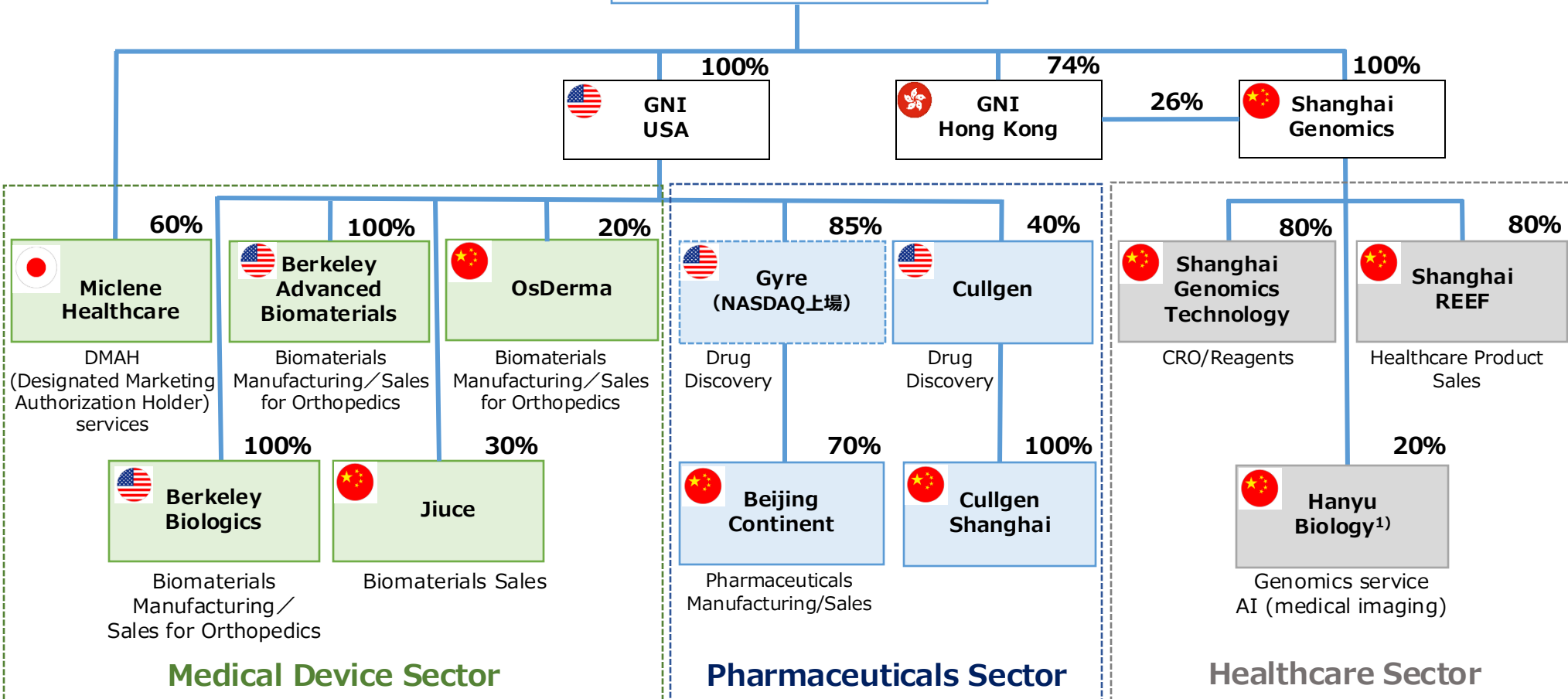
## GNI Group in a nutshell

While maintaining high growth potential  
(**Growth Stock**)

Rich in assets and possessing aspects of  
undervalued stocks (**Value Stock**)

## 7. Supplementary Materials

# Core Group Companies



1) Held for trading

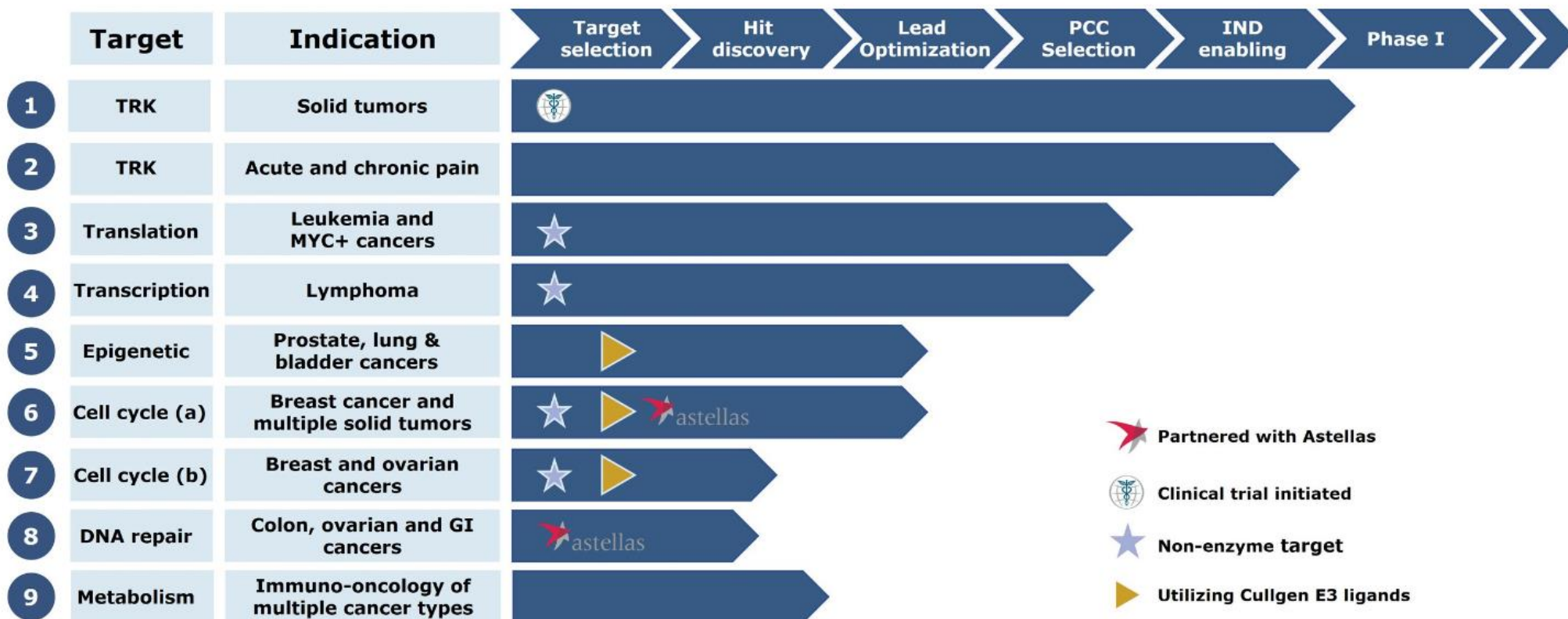


# GYRE / BC Pipeline

## Innovative pipeline as a leader in anti-fibrotic therapies

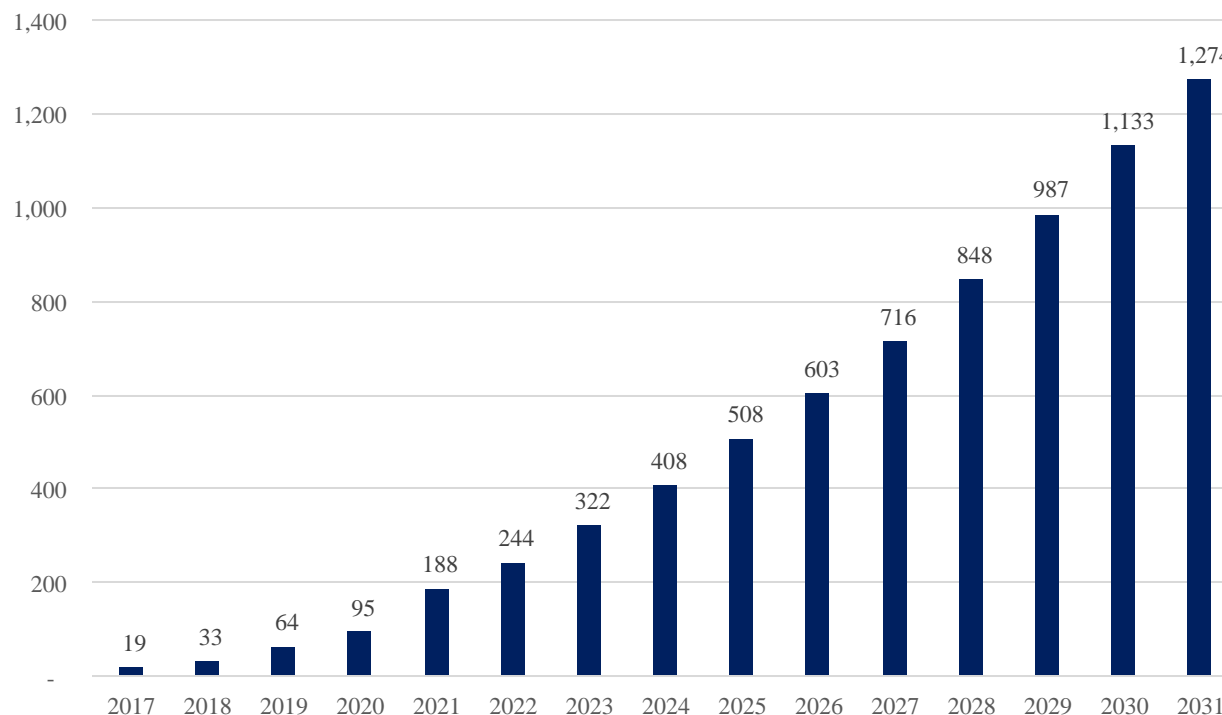
| Candidate             | Indication  | Preclinical | Phase 1 | Phase 2 | Phase 3 | Marketed | Location           |
|-----------------------|---|-------------|---------|---------|---------|----------|--------------------|
| Hydronidone (F351)    | Liver Fibrosis associated with MASH                               | ▶           |         |         |         |          | United States      |
|                       | Chronic Hepatitis B Liver Fibrosis                                | ▶           |         |         |         |          | China <sup>1</sup> |
| Etuary® (Pirfenidone) | Idiopathic Pulmonary Fibrosis (IPF)                               | ▶           |         |         |         |          |                    |
|                       | Dermatomyositis Interstitial Lung Disease (DM-ILD)                | ▶           |         |         |         |          |                    |
|                       | Systemic Sclerosis-associated Interstitial Lung Disease (SSc-ILD) | ▶           |         |         |         |          |                    |
|                       | Pneumoconiosis  | ▶           |         |         |         |          |                    |
|                       | Diabetic Kidney Disease (DKD)                                     | ▶           |         |         |         |          |                    |
| F573                  | ALF/ACLF  | ▶           |         |         |         |          |                    |
| F528                  | Chronic Obstructive Pulmonary Disease (COPD)                      | ▶           |         |         |         |          |                    |
| F230                  | Pulmonary Arterial Hypertension (PAH)                             | ▶           |         |         |         |          |                    |

# Cullgen Pipeline



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

(100 Million JPY)



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

# F351 Phase II Top-line Data Overview (1/3)

## Efficacy Results

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

Source: GNI disclosure on Oct. 23, 2020

## 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+<br>As of 52nd week (FAS) | 1<br>(1/4, 25%)       | 12<br>(12/15,80%)     |
| Ishak score down by 1+<br>As of 52nd week (PPS) | 1<br>(1/4, 25%)       | 12<br>(12/14,85.71%)  |
| p value   | FAS:0.0407、PPS:0.0201 |                       |
| Ratio Difference<br>(Placebo - F351)% & 95% CI  |                       | FAS:                  |
|   |                       | -55.00 (-79.20,-3.49) |
|   |                       | PPS:                  |
|   |                       | -60.71 (-83.59,-8.97) |

Source: GNI disclosure on Oct. 23, 2020

## 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, 2020

# Contact Info:

## GNI Group Ltd.

### Investor Relations

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

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