GNI Group Ltd.

FY2023 Q2 Financial Results Corporate Presentation August 17, 2023

Ying Luo
President and Chief Executive Officer

Securities Code: 2160

We Bring New Hope to Life.

Contents

1. Company Profile

GNI Group Company Profile

Head Office Address
〒103-0023
2-2-2 Nihonbashi-Honcho, Chuo-ku, Tokyo
Nihonbashi Honcho YS Bldg. 3F

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

Establishment
November 2001

President and CEO
Ying Luo, Ph.D.

Capital Stock
10,896 Million yen (as of June 30, 2023)

Number of employees (group-wide)
758 (as of June 30, 2023)

Listing
TSE Growth Market
(Listed in August 2007 / Security Code: 2160)

Main Locations
Japan, the US, China

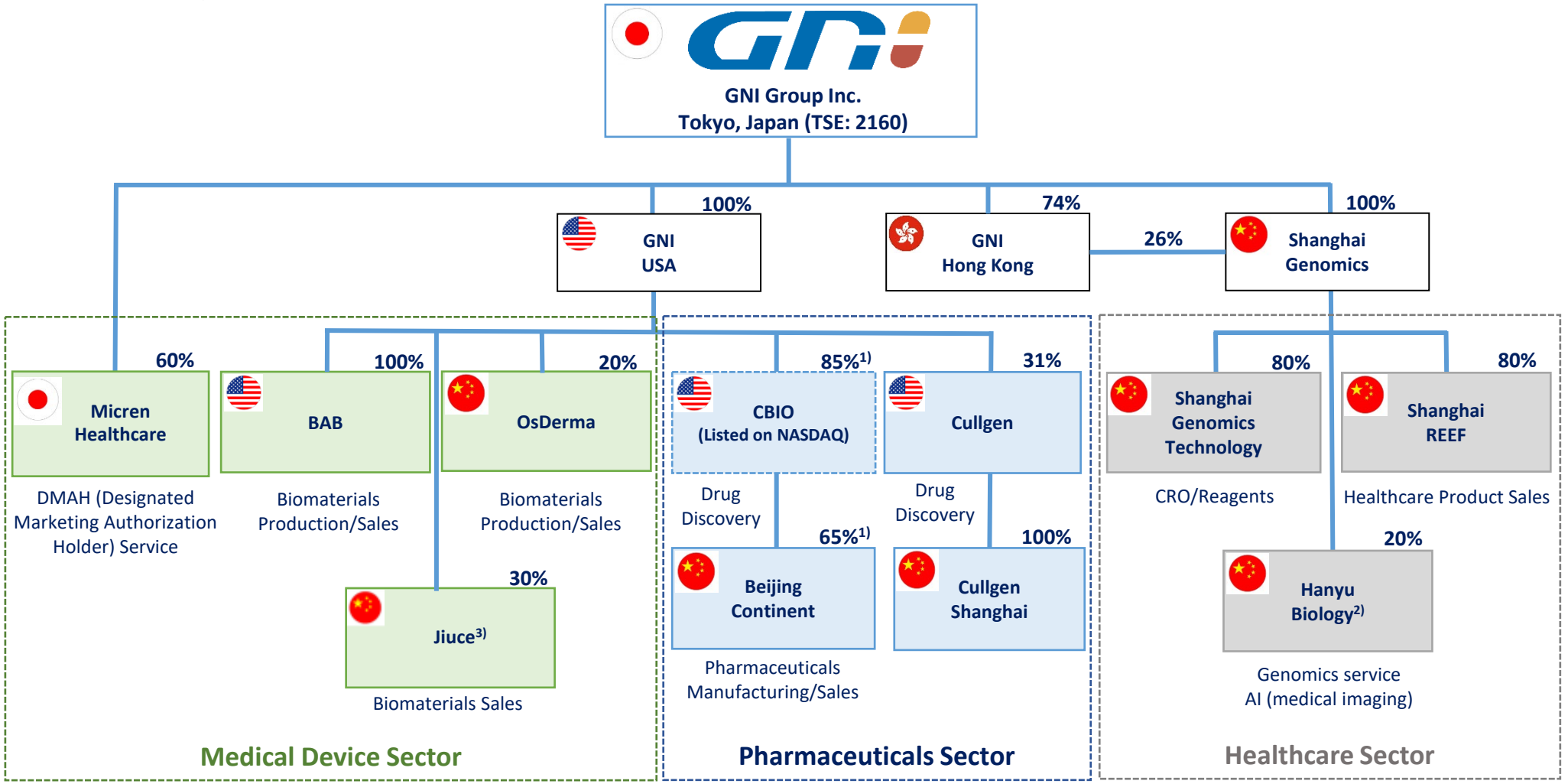
Director, Representative Executive Officer, President and CEO

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.

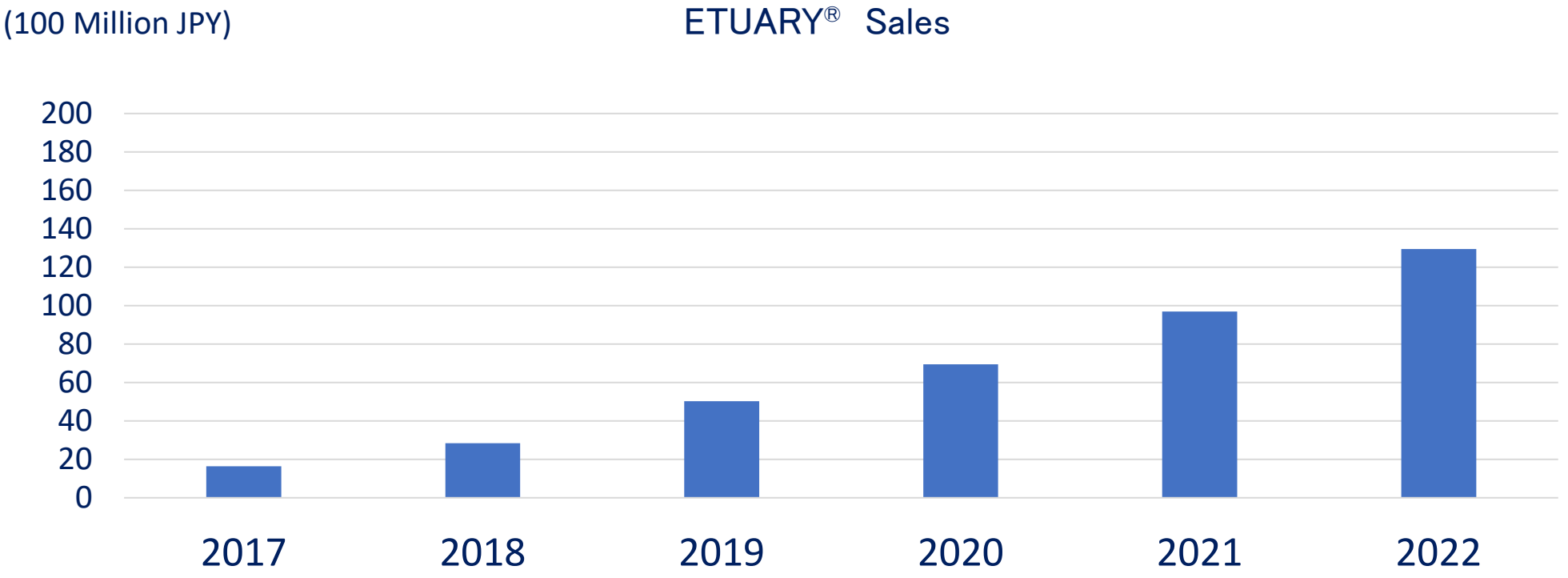
Group Structure



1) After approval of CBIO's (Catalyst Biosciences, Inc.) shareholders' meeting (scheduled on August 29). Currently 17%, 56%, respectively.
2) Not equity method (pure investment)
3) Planning to apply equity method from 2023Q2

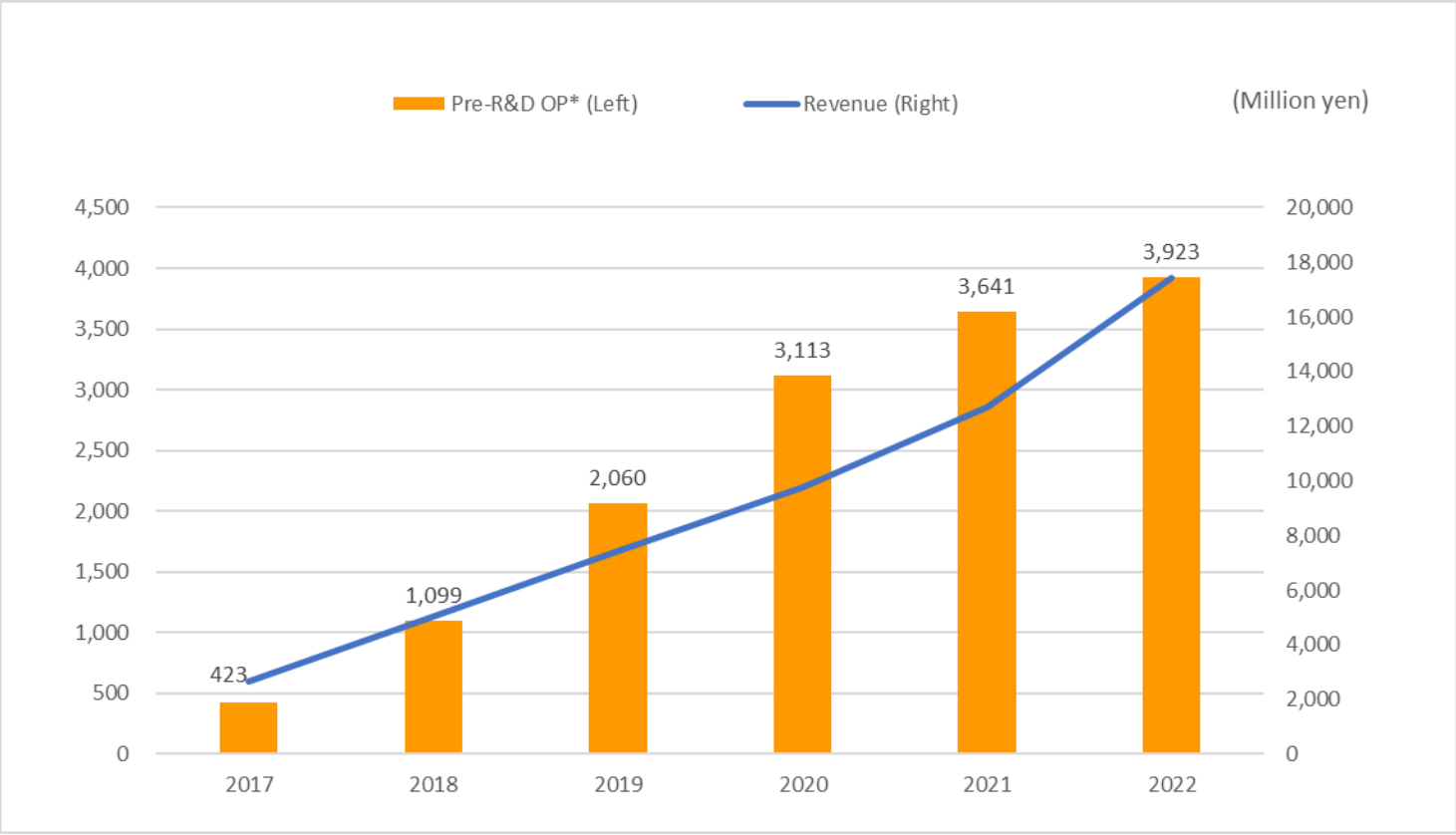
What is GNI Group (1)

From Drug Discovery Success to Pharmaceuticals



What is GNI Group (2)

Unique Profitable Drug Discovery Company



*: Pre-R&D OP = Operating Profit + R&D Expense

High Development Capabilities Recognized by Global Pharmas

Concluded a major contract with Astellas totaling approximately 300 billion yen.
(Cullgen, a subsidiary)

Received investment from AstraZeneca fund
(Cullgen, a subsidiary)

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

✓ Operates globally in the US 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

P/L Summary

Significant year-on-year increase in sales and profit
Record sales and profit

(Million yen)

	2022Q2 YTD	Ratio (vs Revenue)	2023Q2 YTD	Ratio (vs Revenue)	YoY
Revenue	8,154	100.0%	14,096	100.0%	72.9%
Gross profit	7,020	86.1%	12,755	90.5%	81.7%
SG&A	4,765	58.4%	6,179	43.8%	29.7%
R&D	1,089	13.4%	1,253	8.9%	15.1%
Operating profit	1,004	12.3%	**5,476**	38.8%	445.1%
Pretax profit	790	9.7%	5,117	36.3%	547.5%
Net profit	197	2.4%	**4,014**	28.5%	1928.1%
Net profit to the parent	676	8.3%	1,658	11.8%	145.2%

B/S Summary

Significant increase in liquidity on hand

(Million yen)

	2020	2021	2022	2023	20 vs 21	21 vs 22	22 vs 23
Non-current assets	10,194	12,109	16,759	20,232	18.8%	38.4%	20.7%
Current assets	13,024	18,187	17,147	24,818	39.6%	-5.7%	44.7%
Total assets	**23,219**	**30,296**	**33,906**	**45,050**	**30.5%**	**11.9%**	**32.9%**
Non-current liabilities	3,846	8,487	10,592	15,694	120.6%	24.8%	48.2%
Current liabilities	6,603	2,543	3,503	4,557	-61.5%	37.8%	30.1%
Total liabilities	**10,450**	**11,030**	**14,096**	**20,252**	**5.6%**	**27.8%**	**43.7%**
Capital Stock etc.	11,859	17,108	17,125	16,341	44.3%	0.1%	(4.6%)
Retained earnings	(608)	307	696	2,355	-	126.4%	238.2%
Other components of equity	(251)	1,444	3,147	4,279	-	118.0%	36.0%
Attributable to the parent	11,000	18,860	20,969	22,976	71.5%	11.2%	9.6%
Non-controlling interests	1,769	405	(1,158)	1,821	-77.1%	-	-
Total equity	**12,769**	**19,266**	**19,810**	**24,798**	**50.9%**	**2.8%**	**25.2%**

Major Subsidiaries

Name / Acronym	Official Name/Description	% of GNI consolidated revenue (FY 2022)	% of GNI consolidated revenue (FY 2022 H1)
BAB	**Berkeley Advanced Biomaterials LLC** Biomaterials business in the US (Medical Device Segment)	14%	9% (Black)
BC	**Beijing Continent Pharmaceuticals Co.** Drug discovery and pharmaceutical business in China Sales channel with over 500 MRs	77%	52% (Black)
Cullgen	**Cullgen Inc. and Cullgen (Shanghai), Inc.** Drug discovery business in the US and China Partnering with Astellas	0%	34% (Black)

3. First Half Year Topics

Topic 1

Signed a major contract with Astellas

(1) Proof of Cullgen's high-caliber R&D capabilities

(2) Cullgen turning profitable
= All three major subsidiaries in the black

(3) Increase in revenue in the US
= The US share increased to 42.5%

(4) Rights to receive milestone payments depending on the R&D progress in the future
= Another source of stable income

Topic 2

Investment from AstraZeneca Fund

(1) Proof of high drug development capability
＝Possibility of partnering with new global pharmaceutical companies in the future

(2) Securing development funds
= Faster pace of TPD# drug development

#: Targeted Protein Degradation

The above 2 points lay

the groundwork for the potential future listing of Cullgen

Topic 3

Strong ETUARY® Sales

① Sales

2022Q2 YTD		2023Q2 YTD
JPY 6.3 Billion	→	JPY 7.3 Billion

② Further Expansion

= Actively progressing clinical trials to expand the indications in order to meet various needs

4. Upward Revision of Full-Year Forecasts

Upward revision of full-year forecast

(1) Strong ETUARY® Sales

(2) A strategic partnership between Cullgen and Astellas

	Previous Forecast (A)	Revised Forecast (B)	Difference (B-A)	Difference in Ratio (%)	(Ref) 2022 Actual
Revenue (JPY Million)	17,100～20,900	**25,273**	4,373～8,173	20.9%～47.8%	17,418
Operating Profit (JPY Million)	700～1,400	**5,991**	4,591～5,291	327.9%～755.9%	1,377
Profit Before Tax(JPY Million)	(100)～200	**4,143**	3,943～4,243	～1971.5%	767
Profit for the Year(JPY Million)	(500)～0	**2,174**	2,174～2,674	-	(868)
Profit Attributable to Parent (JPY Million)	1,100～1,400	**1,703**	303～603	21.6%～54.8%	388
EPS (JPY)	22.30～33.41	**35.86**	-	-	8.19

FX rate used in the revised forecast: 1 USD = 130.77 JPY / 1 RMB = 19.38 JPY

5. Second Half Year Topics

Topic 1

To become majority shareholder of Catalyst Biosciences* (NASDAQ: CBIO)

(1) Nasdaq-listed company under GNI's consolidation

-> Establish a foothold in the US to become a global biopharma

-> Obtain global valuation

(2) CBIO will acquire an indirect controlling interest in BC*#

-> Expand operation in the US in the future

(3) Accelerate liver fibrosis clinical development in the US

*subject to CBIO shareholder approval # subject to regulatory approvals in the US and China

Topic 2

Completing F351 Phase III Clinical Trial Enrollment

(1) Added 63 subjects in 2023 Q2
-> 91 more subjects to reach the target of 248

(2) Target to disclose the results in late 2024

(3) Plan commercial launch in 2025 after Chinese authority's approval

F351 is a promising drug candidate for the treatment of liver fibrosis, for which there are no approved drugs yet, and a potential blockbuster compound if clinical trials are successful.

6. Supplementary Materials

BC's Development Pipeline

Beijing Continent pharmaceutical co. ltd

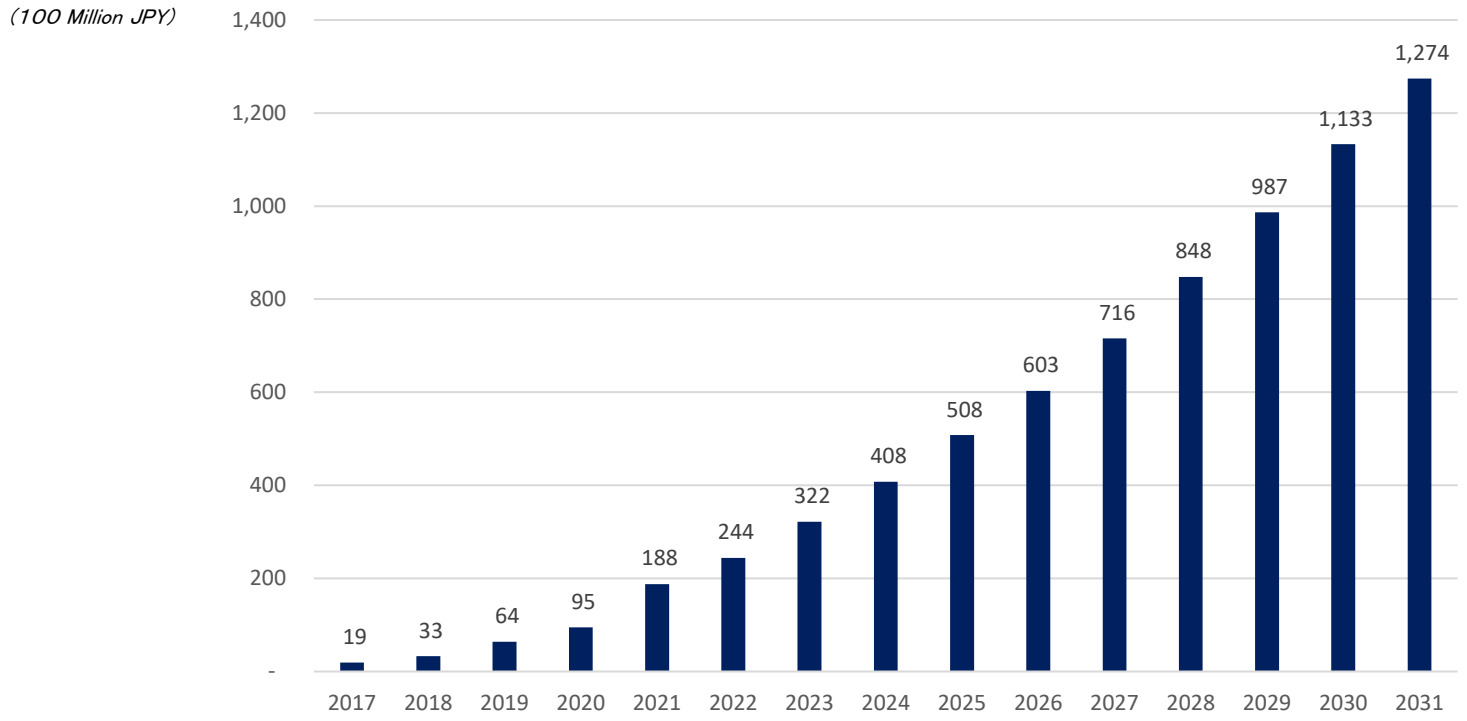
Product			Indication		Preclinical	Phase I	Phase II	Phase III	NDA
Pulmonary Diseases	Fibrosis-associated	ETUARY® (Pirfenidone)	Dermatomyositis Interstitial Lung disease (DM-ILD)	★					
			Systemic Sclerosis-associated Interstitial Lung Disease (SSc -ILD)	★					
			Pneumoconiosis						
	Others	F528	Chronic Obstructive Pulmonary Disease (COPD)						
		F230	Pulmonary Arterial Hypertension (PAH)	★					
Liver Diseases	Fibrosis	F351 (Hydronidone)	Chronic Hepatitis B Liver 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

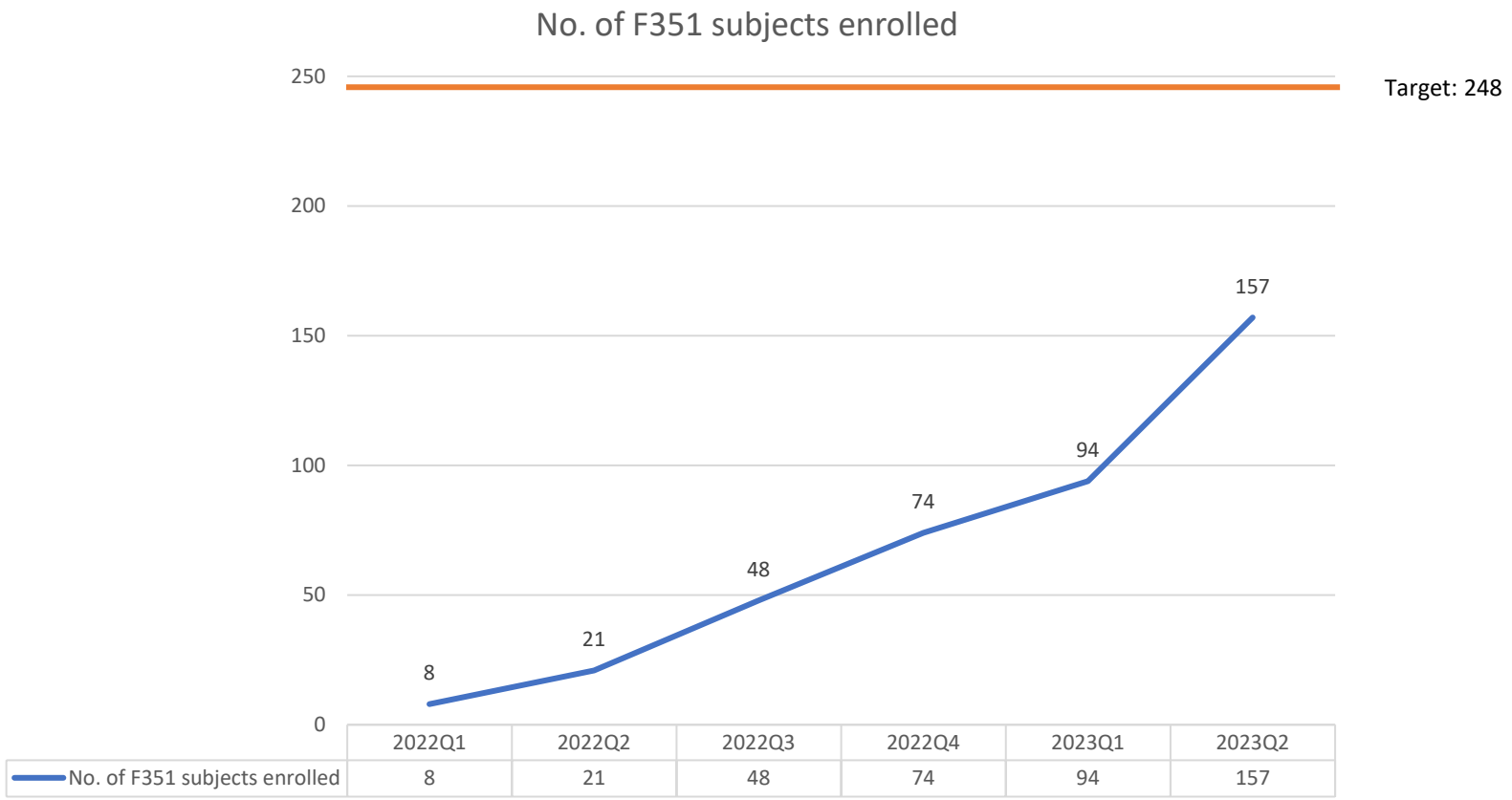
Target Area	Indication	preclinical	Phase I	Phase II	Phase III	NDA
Cell cycle (a)	Breast, pancreatic, lung cancer, malignant melanoma, novel immunotherapeutics					
Cell cycle (b)	Breast and ovarian cancer					
Epigenetics	Prostate and bladder cancer					
Metabolism	Novel Immunotherapeutics					
Tropomyosin 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(R): Pulmonary Fibrosis Drugs Market in China



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

F351 subject enrollment since Phase III launch in 2022 Jan



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: -14.89 (-33.32,4.99)	FAS: -30.52 (-48.12,-9.50)	FAS: -18.32 (-36.76,1.96)
		PPS: -21.03 (-40.20,0.26)	PPS: -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:

GNI Group Ltd.

Investor Relations

: IR@gnipharma.com

: www.gnipharma.com

This presentation contains statements concerning the current plans, expectations and strategies of GNI Group Ltd. (GNI Group). Any statements contained herein that pertain to future operating performance and that are not historic facts are forward-looking statements. Forward-looking statements may include, but are not limited to, words such as “believe,” “plan,” “strategy,” “expect,” “forecast,” “possibility” and similar words that describe future operating activities, business performance, events or conditions. Forward-looking statements, whether spoken or written, are based on judgments made by the management of GNI Group, based on information that is currently available to it. As such, these forward-looking statements are subject to various risks and uncertainties, and actual business results may vary substantially from the forecasts expressed or implied in forward-looking statements. Consequently, investors are cautioned not to place undue reliance on forward-looking statements.

The information contained in this presentation does not constitute or form part of any offer for sale or subscription of or solicitation or invitation of any offer to buy or subscribe for any securities, nor shall it or any part of it form the basis of or be relied on in connection with any contract or commitment whatsoever. Any decision to invest in or acquire securities of GNI Group must be based wholly on the information contained in the preliminary offering circular issued or to be issued by GNI Group in connection with any such offer and not on the contents hereof.

This English summary translation is for reference purposes only. To the extent there is any discrepancy between this English translation and the original Japanese version, please refer to the Japanese version.

Securities Code: 2160