



# GNI Group Ltd.

FY2023 Q1 Financial Results  
Corporate Presentation

May 18, 2023

We Bring New Hope to Patients.

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Chief Financial Officer

Securities Code: 2160

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## Q1 2023 Business Highlights (1/3)

Stable performance overall, but higher expenses pushed down consolidated profits.  
Annual forecast remains unchanged

- ✓ BC and BAB continue to be profitable
- ✓ Healthy cash flow and liquidity

### **Factors that pushed down profits:**

- ✓ Higher expenses from
  - Significant R&D increase in Cullgen
  - Increasing sales and marketing headcounts in China
- ✓ One-time items
  - M&A-related fees
  - CBIO stock price drop after cash dividend distribution to CBIO shareholders

Abbreviations are explained at the beginning of the supplemental material.

# Q1 2023 Business Highlights (2/3)

## R&D Making Steady Progress

### BC

✓ F351 subject enrollment in Ph III clinical trial passed mid-point

✓ F573 Ph II clinical trial commenced

### Cullgen

✓ TRK degrader clinical trial approved by HGRAC

### CBIO

✓ F351 NASH Ph IIa trial outline disclosed

## Q1 2023 Business Highlights (3/3)

### Strategic Initiatives towards Business Expansion

#### Pharmaceutical Segment

- ✓ Transactions with CBIO on track
- ✓ Cullgen's successful funding led by an AstraZeneca-CICC fund
- ✓ Multiple pre-IND studies are on-going in COPD and cancers

#### Medical Device Segment

- ✓ OsDerma expanding BAB's biomaterials to Aesthetics
- ✓ Integrating Micren

**Q1 Business Highlights**

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## What is GNI?

**Balanced drug discovery and profitability**  
**Unique global biopharmaceutical company**

### **Innovative and efficient global platform**

- R&D in the US and China
- + Efficient clinical development in China
- + Commercialization in the US, China and Japan

### **Great growth potential**

by pharmaceuticals, medical devices, healthcare, etc.



# BC's Development Pipeline

Beijing Continent pharmaceuti

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

★ Rare Disease

# CBIO's Development Pipeline

		Product	Indication	Preclinical	Phase I	Phase II	Phase III	NDA	Marketed	Target Countries
Liver Diseases	Fibrosis	F351	Hepatic fibrosis resulting from NASH							US

# Cullgen's Development Pipeline

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

**Q1 Business Highlights**

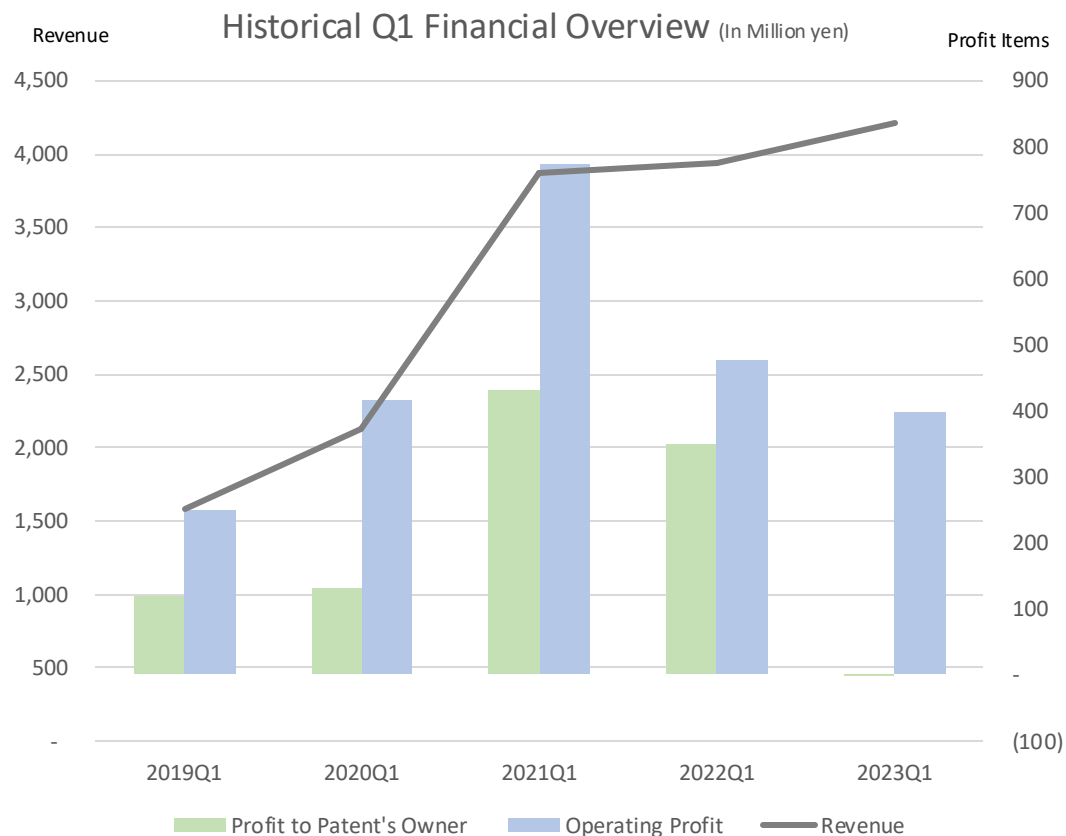
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# 2023Q1 Financial Highlights (1/2)

## Solid Topline Growth in Core Businesses



### Revenue

JPY 4,206 m ↑

YoY  
273 m  
6.9%

### Operating Profit

JPY 397 m ↓

-81 m  
-17.0%

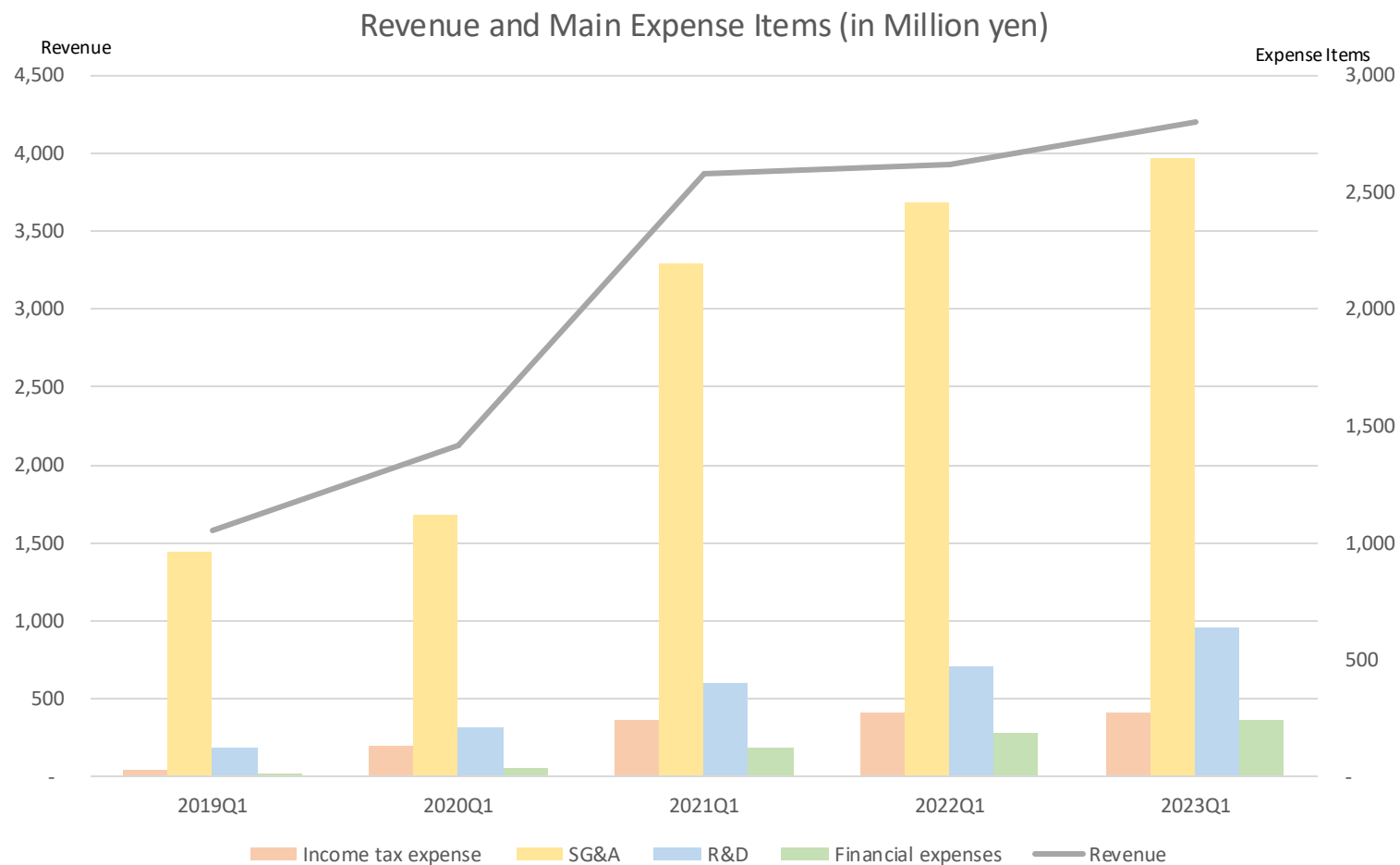
### Profit to Parent's Owner

JPY (2) m ↓

-353 m  
(n/a)

# 2023Q1 Financial Highlights (2/2)

## A closer look at the expense items



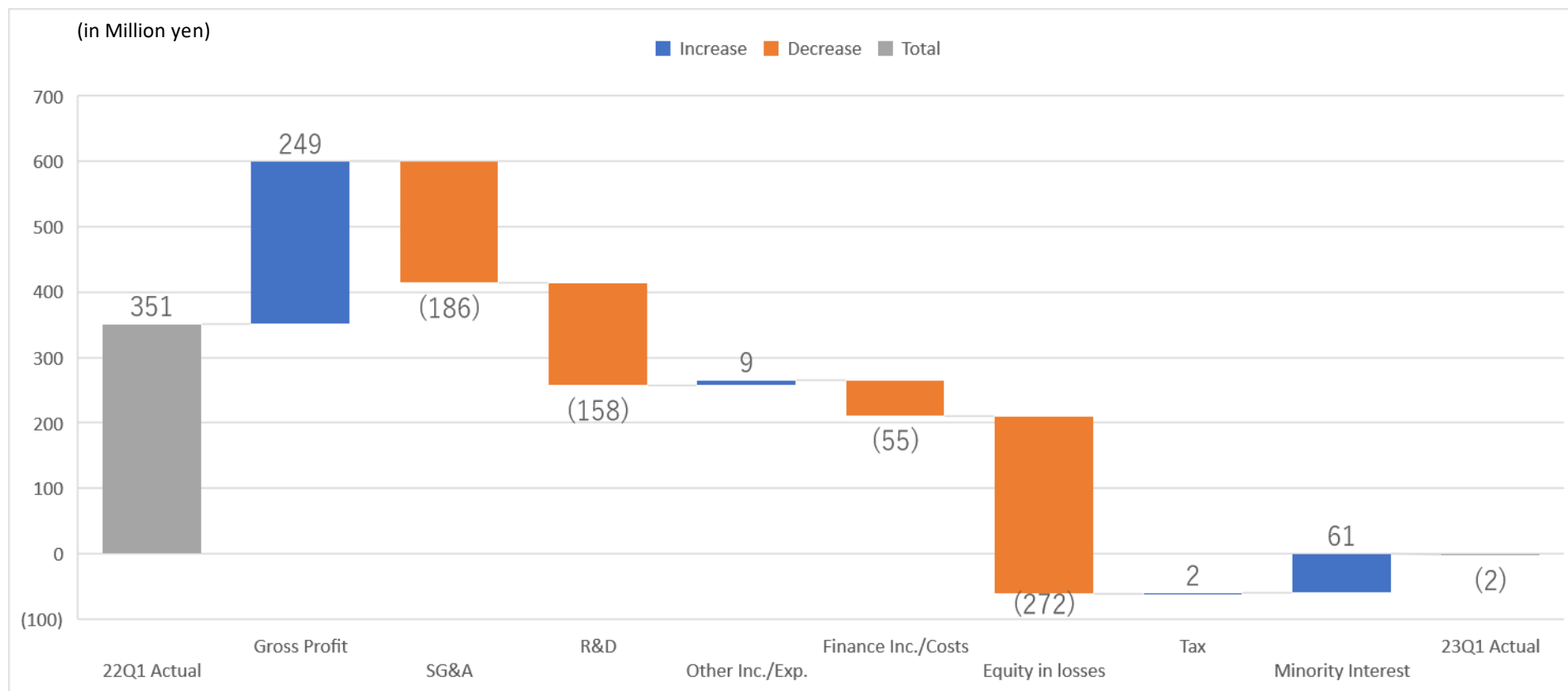
# FY2023Q1 Consolidated P/L Summary

(In Million yen)

	FY22 Q1	Ratio (vs Revenue)	FY23 Q1	Ratio (vs Revenue)	YoY
<b>Revenue</b>	<b>3,933</b>	<b>100.0%</b>	<b>4,206</b>	<b>100.0%</b>	<b>6.9%</b>
<b>Gross profit</b>	<b>3,384</b>	<b>86.0%</b>	<b>3,632</b>	<b>86.4%</b>	<b>7.3%</b>
SG&A	2,458	62.5%	2,646	62.9%	7.6%
R&D	468	11.9%	635	15.1%	35.7%
<b>Operating profit</b>	<b>478</b>	<b>12.2%</b>	<b>397</b>	<b>9.4%</b>	<b>-17.0%</b>
Financial income	54	1.4%	49	1.2%	-9.3%
Financial expenses	186	4.7%	239	5.7%	28.5%
Equity loss of affiliates	-	-	272	6.5%	-
<b>Pretax profit</b>	<b>347</b>	<b>8.8%</b>	<b>-64</b>	<b>-1.5%</b>	<b>-</b>
Tax	275	7.0%	276	6.6%	0.4%
<b>Net profit</b>	<b>72</b>	<b>1.8%</b>	<b>-341</b>	<b>-8.1%</b>	<b>-</b>
<b>Net profit to parent</b>	<b>351</b>	<b>8.9%</b>	<b>-2</b>	<b>-0.0%</b>	<b>-</b>

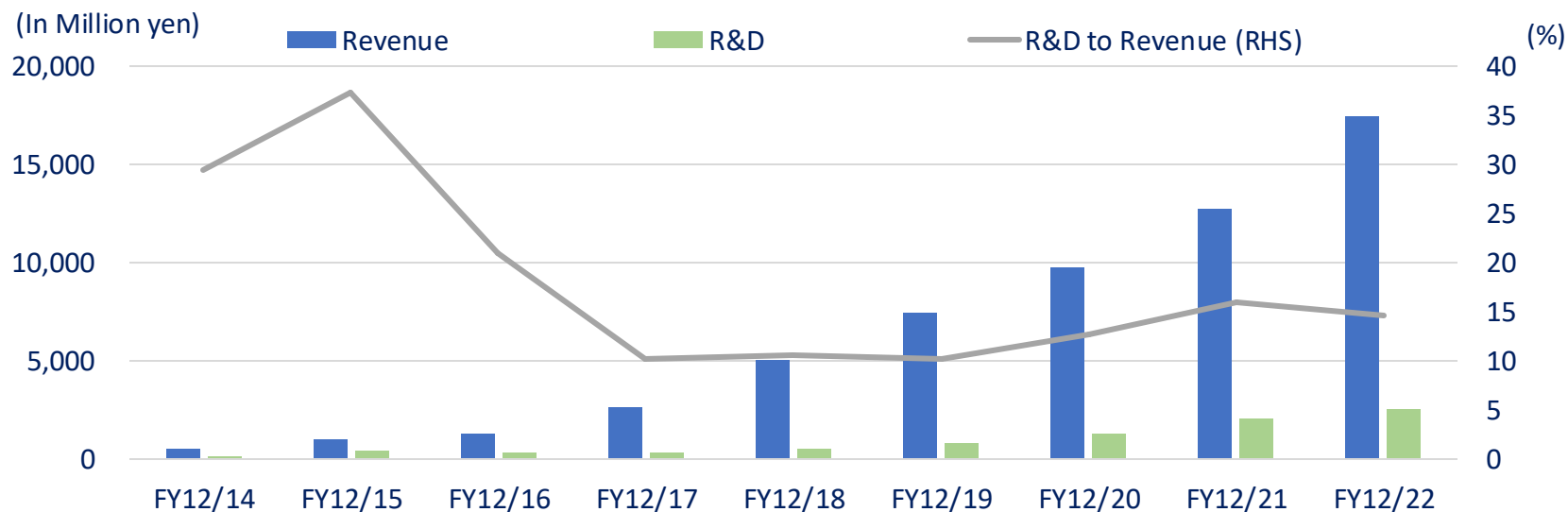
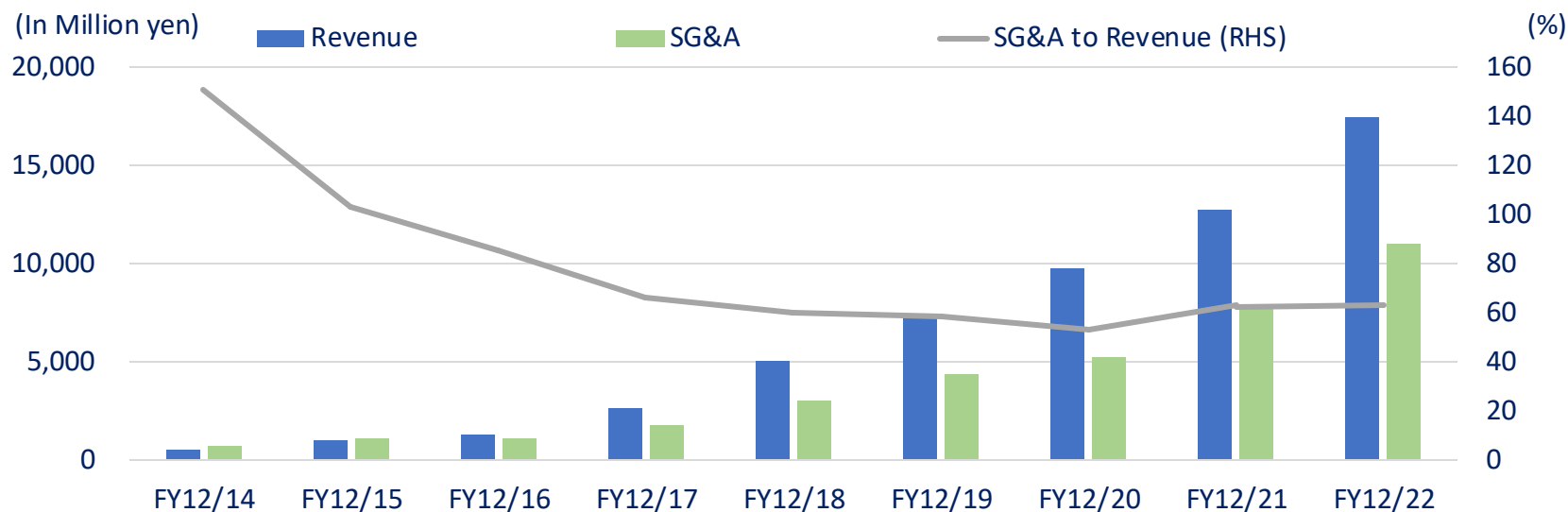
# YoY Change in Profit Attributable to Parent's Owners

Increase in SG&A and R&D as well as devaluation of CBIO due to dividend distribution pushed down the profit





# Consolidated Revenue vs SG&A / R&D Expenses



# Segment Results

## Pharmaceutical

(In Million yen, %)

	FY19 1Q	FY20 1Q	FY21 1Q	FY22 1Q	FY23 1Q
Revenue	1,092	1,693	3,409	3,401	3,606
Operating profit	37	285	600	223	149
Operating profit margin	3.4%	16.8%	17.6%	6.6%	4.1%

## Medical Device

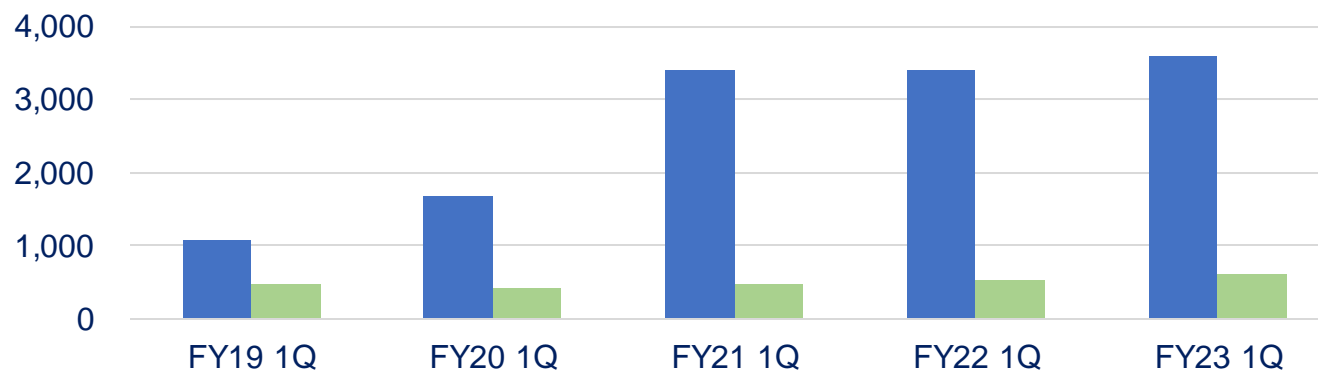
(In Million yen, %)

	FY19 1Q	FY20 1Q	FY21 1Q	FY22 1Q	FY23 1Q
Revenue	482	431	462	531	599
Operating profit	187	130	173	255	248
Operating profit margin	38.8%	30.2%	37.4%	48.0%	41.4%

(In Million yen)

■ Pharmaceutical

■ Medical Device



**Q1 Business Highlights**

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## Explanation of Terms

Terminology	Description
BAB	Berkeley Advanced Biomaterials LLC
BC	Beijing Continent Pharmaceuticals Co., Ltd
Cullgen	Cullgen Inc. and Cullgen (Shanghai), Inc.
CBIO	Catalyst Biosciences, Inc.
IND	Investigational New Drug
NMPA	National Medical Products Administration, China
NRDL	China's National Reimbursement Drug List
NASH	Nonalcoholic steatohepatitis
TPD	Targeted Protein Degradation
TRK	Tropomyosin Receptor Kinase
uSMITE™	Cullgen's proprietary platform for targeted protein degradation induction technology ( <b>U</b> biquitin-mediated, <b>S</b> mall <b>M</b> olecule- <b>I</b> nduced <b>T</b> arget <b>E</b> limination technology)
The Company / We	GNI Group Ltd.
The Group	The Company and its subsidiaries and affiliates

# Exchange Rates

(in JPY)

Date	B/S		P/L	
	US\$	RMB	US\$	RMB
FY2014	120.55	19.35	90.71	14.16
FY2015	120.61	18.36	113.41	14.90
FY2016	116.49	16.76	115.24	17.80
FY2017	113.00	17.29	112.39	16.64
FY2018	111.00	16.16	110.57	16.69
FY2019	109.56	15.67	109.43	15.85
2019Q1	110.99	16.47	110.46	16.37
2020Q1	108.83	15.31	109.22	15.56
2020Q2	107.74	15.23	108.43	15.37
2020Q3	105.80	15.54	107.48	15.34
2020Q4	103.50	15.88	106.67	15.44
2021Q1	110.71	16.84	106.24	16.31
2021Q2	110.58	17.11	107.74	16.63
2021Q3	111.92	17.30	108.55	16.77
2021Q4	115.02	18.06	109.84	17.03
2022Q1	122.39	19.26	117.10	18.43
2022Q2	136.68	20.38	123.16	18.98
2022Q3	144.81	20.37	128.02	19.32
2022Q4	132.70	19.01	130.77	19.38
2023Q1	133.53	19.42	133.25	19.32

## Consolidated B/S Snapshot

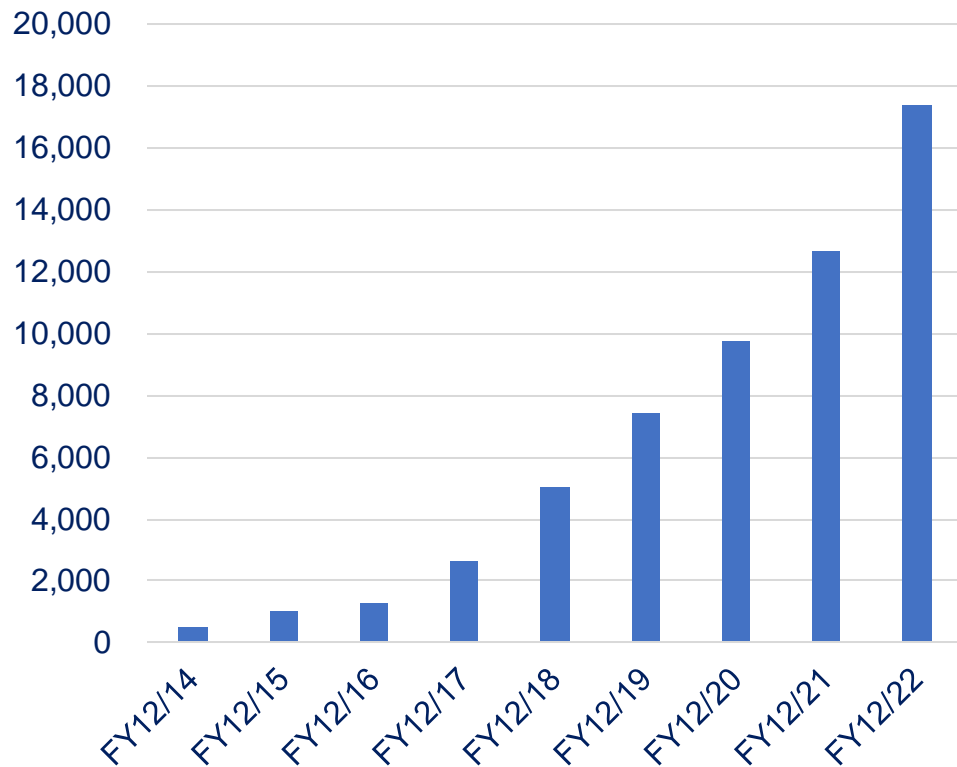
(In Million yen, %)

	FY2020	FY2021	FY2022	23Q1	20 vs 21	21 vs 22	22 vs 23
Non-current assets	10,194	12,109	16,759	17,723	18.8%	38.4%	5.8%
Current assets	13,024	18,187	17,147	16,347	39.6%	-5.7%	-4.7%
<b>Total assets</b>	<b>23,219</b>	<b>30,296</b>	<b>33,906</b>	<b>34,070</b>	<b>30.5%</b>	<b>11.9%</b>	<b>0.5%</b>
Non-current liabilities	3,846	8,487	10,592	10,835	120.7%	24.8%	2.3%
Current liabilities	6,603	2,543	3,503	3,448	-61.5%	37.8%	-1.6%
<b>Total liabilities</b>	<b>10,450</b>	<b>11,030</b>	<b>14,096</b>	<b>14,284</b>	<b>5.6%</b>	<b>27.8%</b>	<b>1.3%</b>
Capital Stock etc	11,859	17,109	17,126	17,130	44.3%	0.1%	0.0%
Retained earnings	(608)	307	696	693	-	126.7%	-0.4%
Other components of equity	(251)	1,444	3,147	3,382	-	117.9%	7.5%
Attributable to owners of the parent	11,000	18,860	20,969	21,205	71.5%	11.2%	1.1%
Non-controlling interests	1,769	408	(1,158)	(1,419)	-76.9%	-	22.5%
<b>Total equity</b>	<b>12,769</b>	<b>19,268</b>	<b>19,810</b>	<b>19,786</b>	<b>50.9%</b>	<b>2.8%</b>	<b>-0.1%</b>

# Consolidated Revenue and Net Income

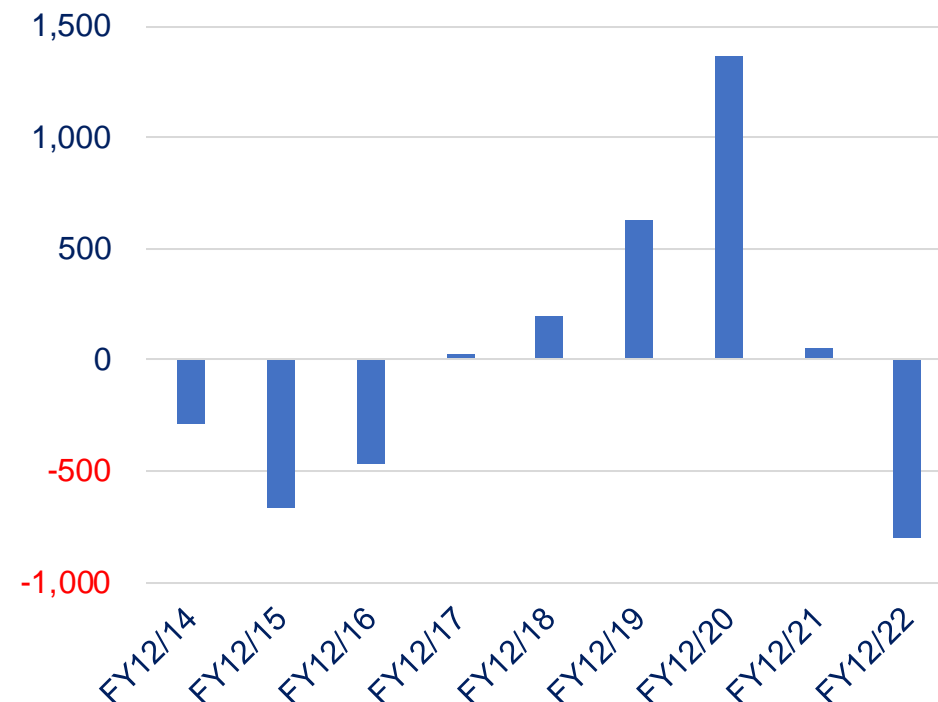
## Revenue

(In Million yen)

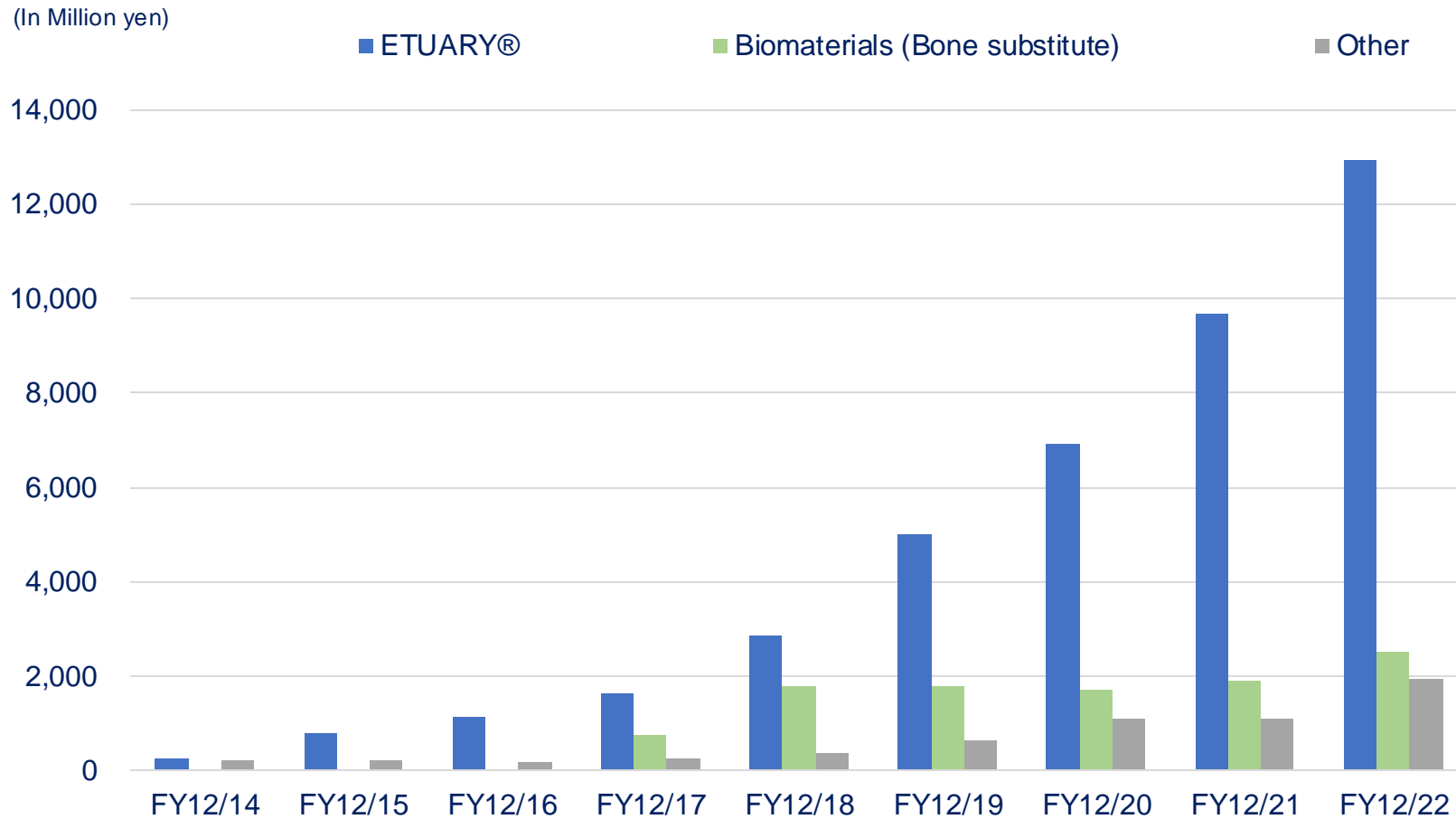


## Net Income

(In Million yen)



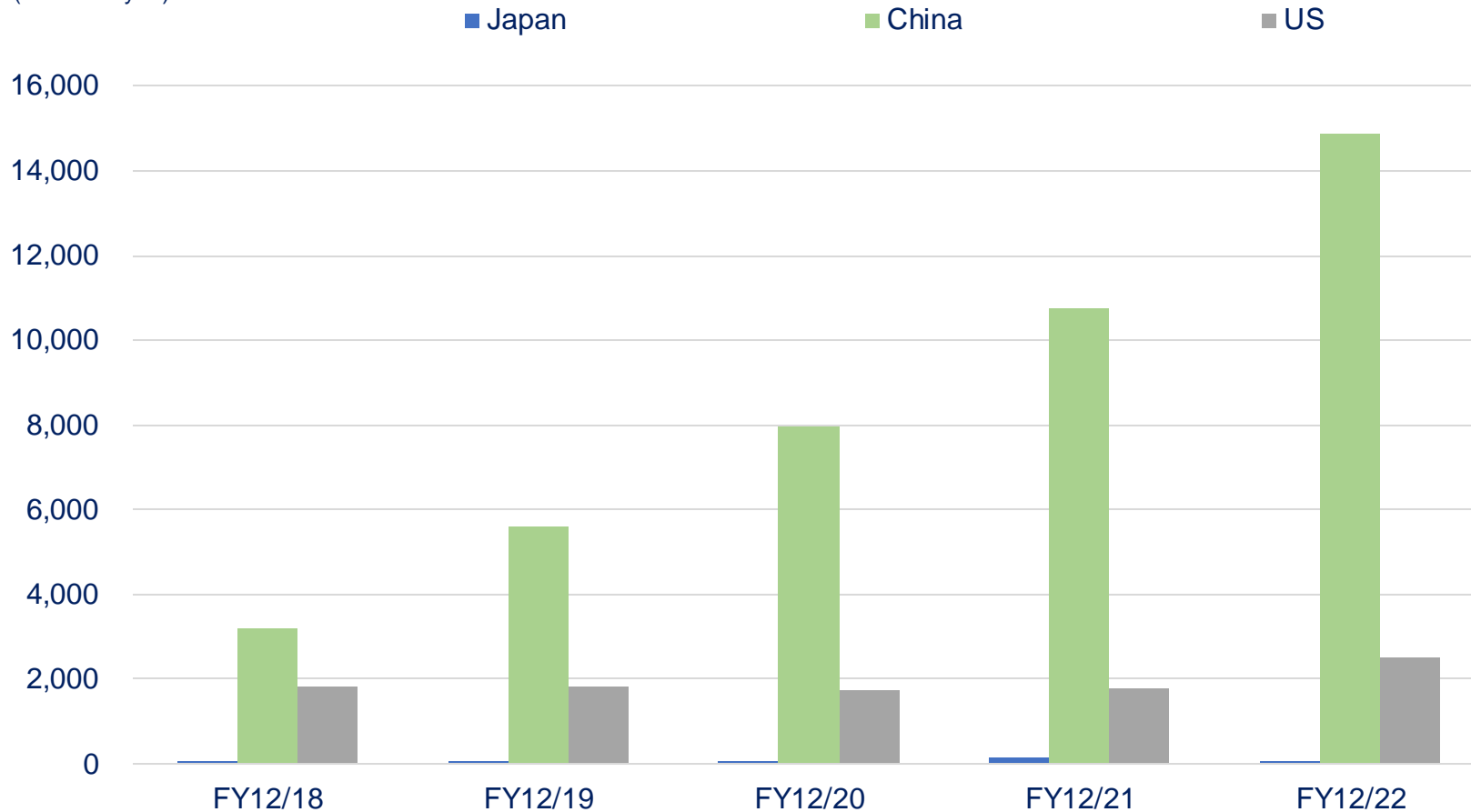
# Revenue by Product



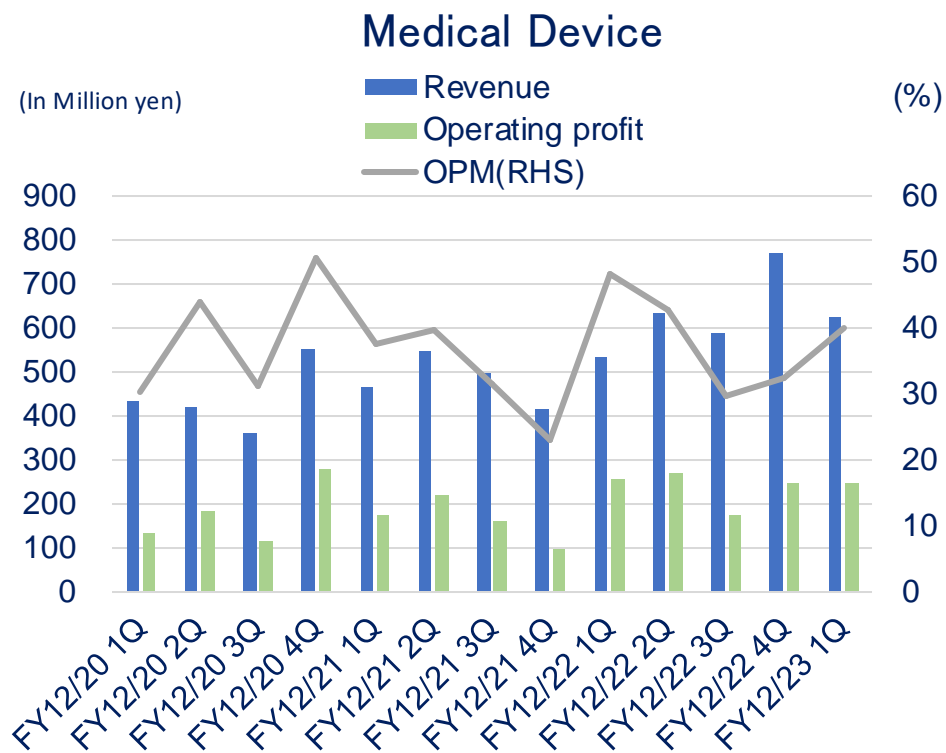
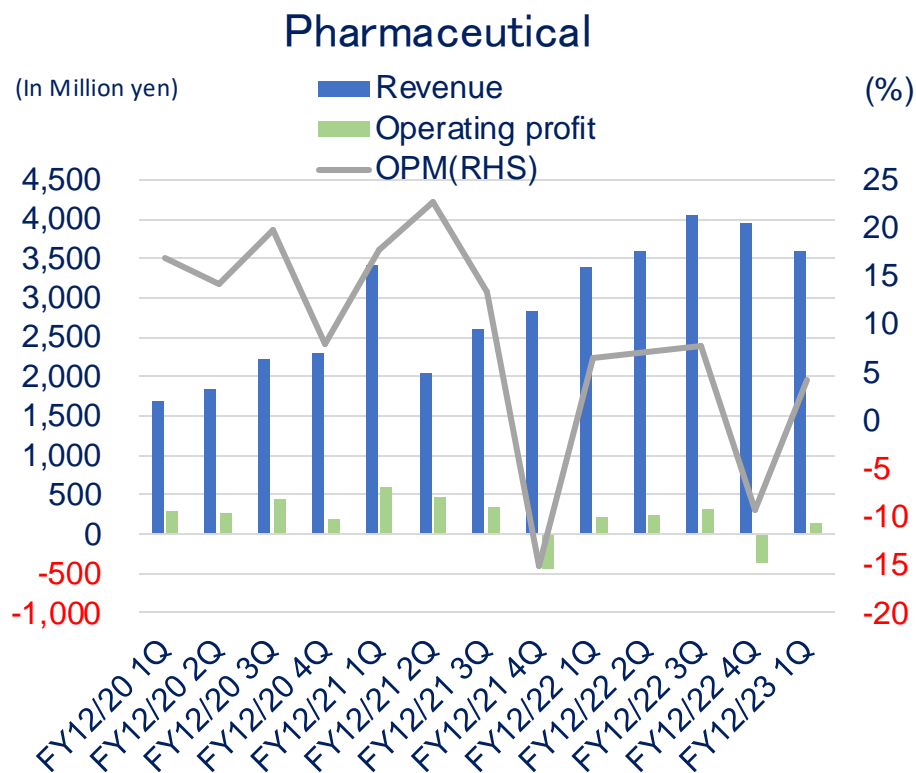


# Revenue by Country

(In Million yen)



# Quarterly Revenue and Profit by Segment



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