



GNI Group Ltd.

# FY2021 Financial Results Corporate Presentation

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We Bring New Hope to Patients

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Securities Code: 2160

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Note: In places, pro forma figures in the pages which follow may be rounded to underscore direction of the business.

## FY2021 Key Developments

### ✓ Research & Development

#### Beijing Continent

**F351** Phase III clinical trial started in Jan 2022 for HBV-induced liver fibrosis targeting commercial launch at or before 2025 in China.

**F573** Phase I clinical trial also started in Jan 2022 for liver failures also in China.

#### Cullgen

Lead PROTAC drug molecule pre-IND consultation with China's NMPA.








### ✓ Corporate Finance

- Consolidated revenue reached JPY12,690 million, the highest in history
- Acquired 100% of BAB LLC
- Completed Series B financing for Cullgen
- Realized significant returns on Reveal Biosciences and IriSys corporate investments

### ✓ Human Capital Investment

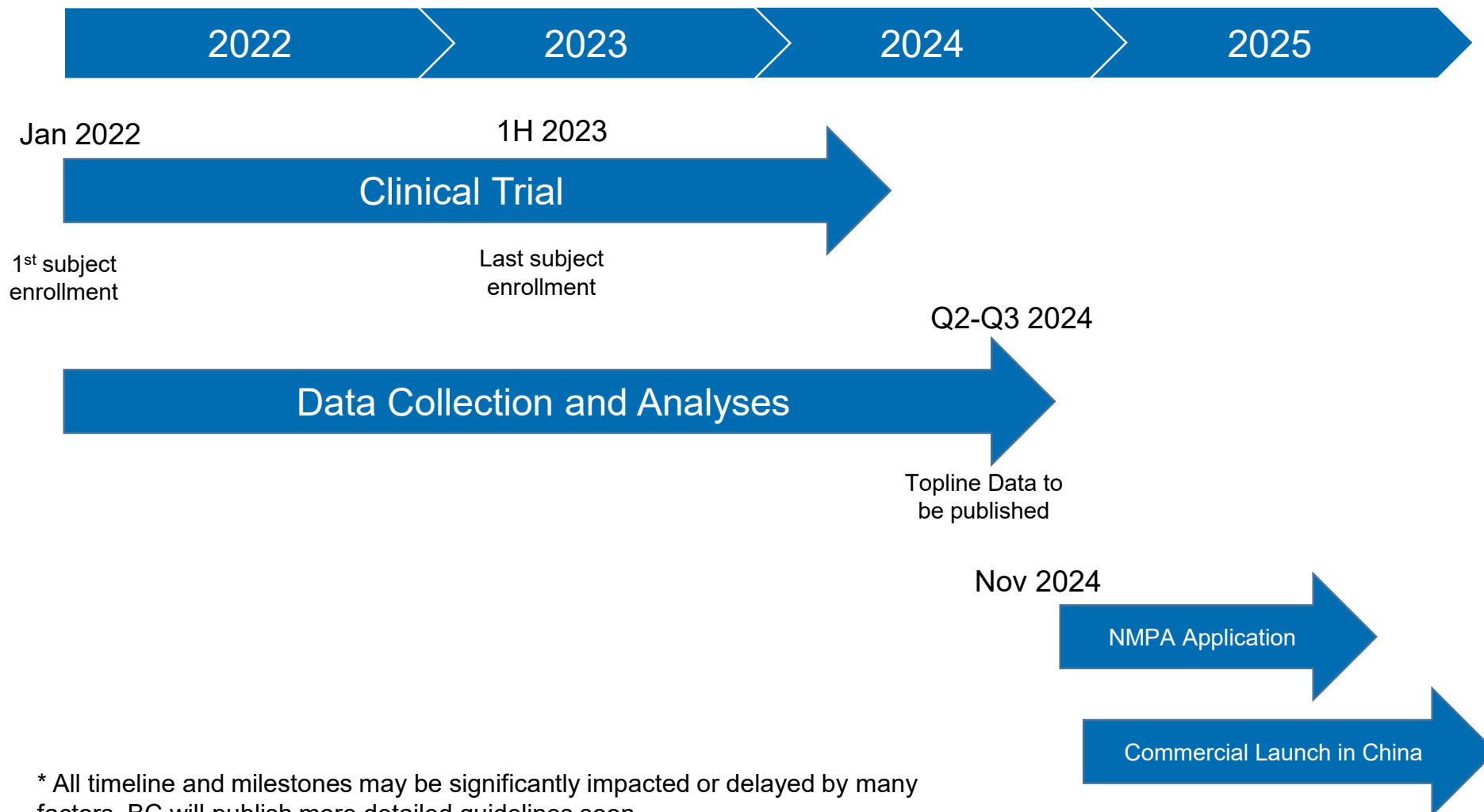
- In Japan at the holding company level, strengthened strategic IR and Finance department
- Increasing top professional R&D staff in China and USA (from 114 to 143)
- Expanding sales and marketing staff in China (from 262 to 299)

## Development : Pipeline Update

Product - Indication	Origin	Phase I	Phase II	Phase III	Latest Status as of 2021 Dec
<b>Etuary® (China)</b>					
- <b>Connective Tissue Disease Associated Interstitial Lung Disease (CTD-ILD)</b>	Proprietary				Dual Phase III clinical trial ongoing for scleroderma (15 subjects) and dermatomyositis (43 subjects)
- <b>Radiation Pneumonitis (RP)</b>	Proprietary				Expanded RP clinical trial ongoing (111 subjects)
- <b>Diabetic Kidney Disease (DKD)</b>	Proprietary				Phase I clinical trial ongoing (24 subjects)
- <b>Pneumoconiosis (PD)</b>	Proprietary				Preparing for Phase III
<b>F351 (China, U.S.)</b>					
- <b>Liver Fibrosis (China)</b>	Proprietary				Phase III clinical trial started in Jan 2022
- <b>Liver Fibrosis (U.S.)</b>	Proprietary				Initiated pre-IND discussion with FDA for NASH Phase II trial in USA
<b>F573 (China)</b>					
- <b>Acute/Acute-on-chronic Liver Failure</b>	License-in				Phase I clinical trial started in Jan 2022
<b>PROTAC (China)</b>					
<b>Cancer</b>	Proprietary				Initiated pre-IND discussion with NMPA for cancer Phase 1 trial

NMPA : National Medical Products Administration (Formerly known as China Food and Drug Administration)  
 FDA : Food and Drug Administration HGRAC : Human Genetic Resource Administration of China

# Development Highlight: F351 Roadmap\*



\* All timeline and milestones may be significantly impacted or delayed by many factors. BC will publish more detailed guidelines soon.

## 2021 Full Year Financial Highlights

### Full-year Consolidated Revenues and Gross Margin increased by 30% and 35% YoY continuing six years running of strong results

- ❑ Ended 2021 in a **strong cash position** at JPY 14.3 Billion vs JPY 10.3 Billion at 2020 end.
- ❑ In China, on the back of our market share for Lung Fibrosis therapeutic drug Etuary® (well above 80%), **Beijing Continent** achieved record revenues, recording RMB 580 Million in 2021, up from RMB 460 Million one year earlier.
- ❑ In the US, **Berkeley Advanced Biomaterials** rebounded from USD 16.5 Million in sales in 2020 in spite of the ongoing challenges of the COVID-19 pandemic to end the year at USD17.4 Million for an increase of 5.7%.

### Operating Profit declined 13% YoY to JPY 1.6 Billion reflecting our continued investment in our most promising portfolio companies

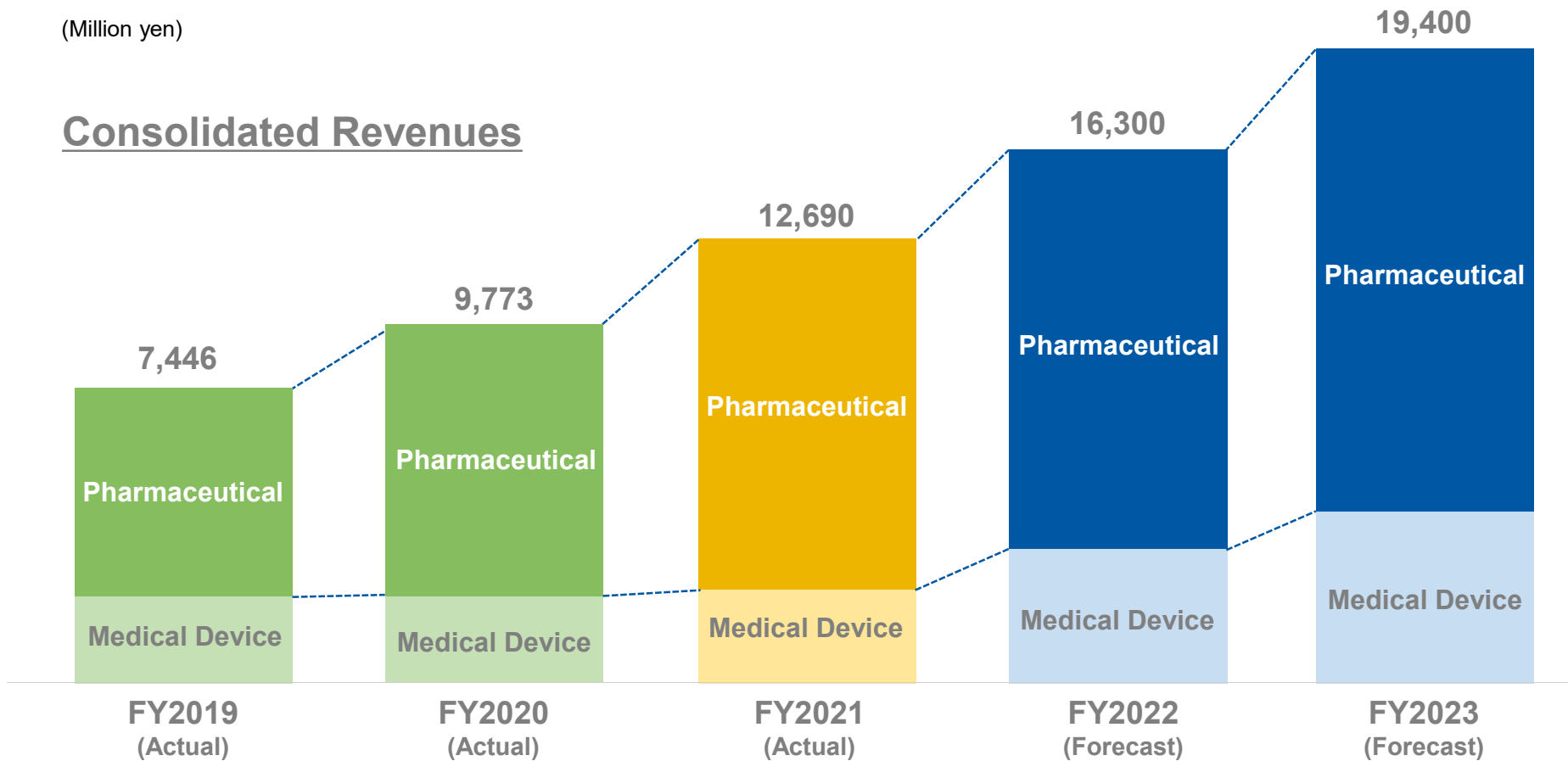
- ❑ Increase in the headcount at Cullgen from 61 staff to 86 strong supporting drug discovery and clinical operations
- ❑ Increased R&D investment in our core subsidiaries, Beijing Continent and Cullgen for clinical trials of F351 and other pipeline drugs
- ❑ Expansion of manufacturing capacity in China to support further drug sales and improve productivity to meet expected demand in the coming years

# Achieved Steady Growth During COVID-19 Pandemic with Promising Outlook



(Million yen)

## Consolidated Revenues



## 2021 Full Year Financial Highlights (continued)

### Core operating businesses have good momentum.

- ❑ Heavy investment in R&D, many one-time/noncash items, and increased marketing cost in 2021 reduced Profit before tax. Such spending has paved the way for expansion in 2022 and 2023.
- ❑ Profit after tax declined 96% to break even under IFRS reporting.

### The story of 2021: significant corporate events, which brought with them important structural changes in our business impacting our IFRS reporting

- ❑ **Non-Cash Interest Charges:** adjusted for such expenses, *normalized net profit* would have reached JPY 660 Million or 12x higher than the IFRS reported profit of JPY 55 Million\*. Such charges are mostly related to an obligation of Cullgen (not GNI Group parent company) to buy back certain investors' shares if there is no IPO.
- ❑ **One-Time Items:** Further adjustments for one-time taxes on gains from the two corporate investments successfully realized and for one-time costs incurred by Beijing Continent as it prepares for an IPO in 2022\*\*, would cause *normalized net profit* to reach JPY 1.1 Billion or 18x higher than the IFRS reported Profit after tax; that is, a decline in reported profit of only 23% rather than 96%.

\* Assumes Cullgen will successfully complete an IPO by the end of 2024

\*\* BC has budgeted additional IPO costs in 2022



## Looking Forward – Various Scenarios

- ❑ **From full consolidation to equity accounting:** the next rounds of funding at Cullgen, for example, would likely trigger deconsolidation and therefore a change on our balance sheet to equity method of accounting; there would also be (beneficial) changes to our IFRS reported PnL:

(JPY Million)	Actual 2020	Actual 2021	Pro Forma 2021 <i>E.g., Cullgen Deconsolidated</i>	Pro Forma 2021 <i>Non-Cash Interest Adjusted</i>
<b>Operating profit</b>	1,869	<b>1,624</b>	3,450	no change
<b>Profit before tax</b>	1,805	<b>1,107</b>	2,970	1,720
<b>Profit for the year</b>	1,365	<b>55</b>	1,920	660

- ❑ **Profit Attributable to GNI Group's Shareholders** however will see no change due to allocation of expenses to the Group's minority interest shareholders.

# FY2021 Summary Consolidated Financials

(JPY Million)

Statements of Income	2020 Actual	2021 Actual	Change
Revenue	9,773	12,690	30%
Gross profit	8,227	11,089	35%
Selling, general and administrative expenses	5,180	7,958	54%
Research and development expenses	1,243	2,015	62%
Operating profit	1,869	1,624	-13%
Finance income	46	129	182%
Finance costs	109	647	491%
Profit before tax	1,805	1,107	39%
Income tax expenses	440	1,051	139%
Profit after tax	1,365	55	-96%
Annual profit attributable to owner of the company	1,258	1,066	-15%

- 6th year of revenue increase, 57% CAGR since 2016
- Increase of personnel in BC and Cullgen, higher marketing expenses in BC
- Ongoing investment in R&D expanding clinical trial operations in China & US
- Factory expansion in China
- Increase in non-cash finance costs at US subsidiary Cullgen (JPY 600 Million)
- One-time taxes due to substantial investment gains realized in 2021 (JPY 220 Million)
- Higher expenses at Cullgen and BC for R&D, marketing, and IPO preparation resulted in decline in profits attributable to GNI.

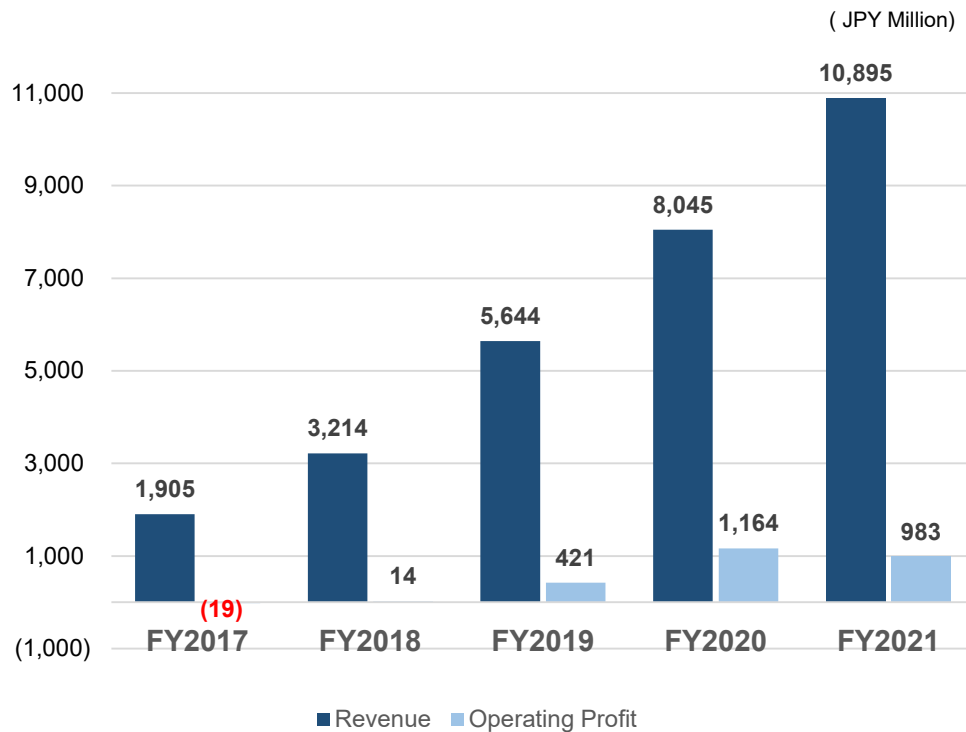
Statements of Financial Position	FY2020 Actual	FY2021 Actual	Change
Cash and cash equivalents	10,322	14,352	39%

- Robust cash position from operations and financing activities

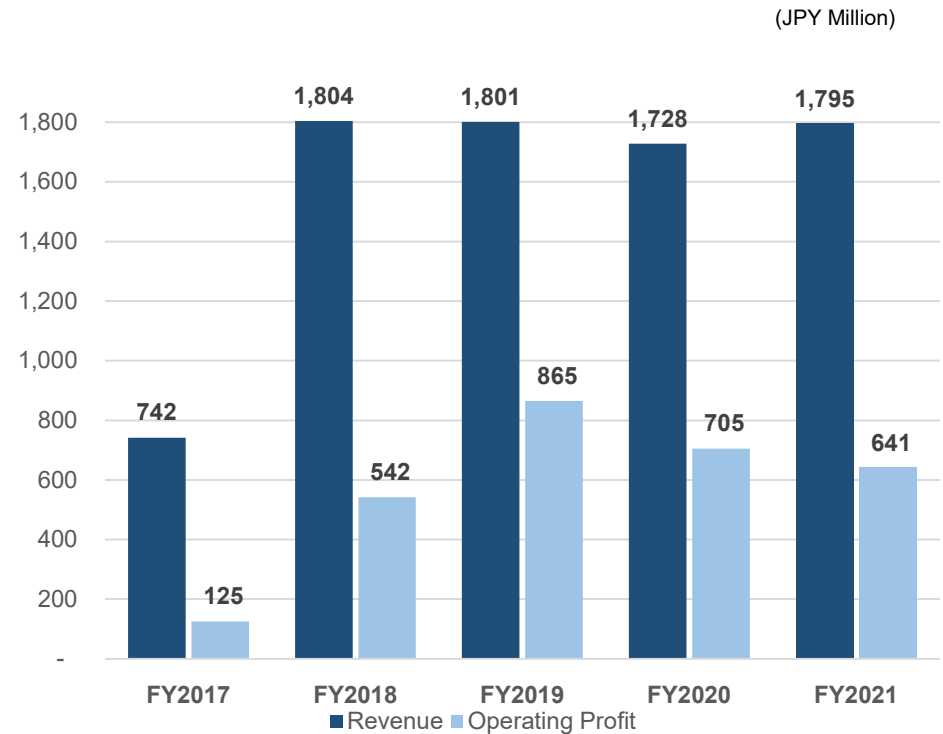
# FY2021 Reports by Segments

Pharmaceutical segment experiencing strong top-line growth while investment continues to expand sales / marketing and R&D; Medical Device segment weathered COVID-19's challenges well, maintaining profitability on higher revenues.

Pharmaceutical Segment Revenue and Operating Profit



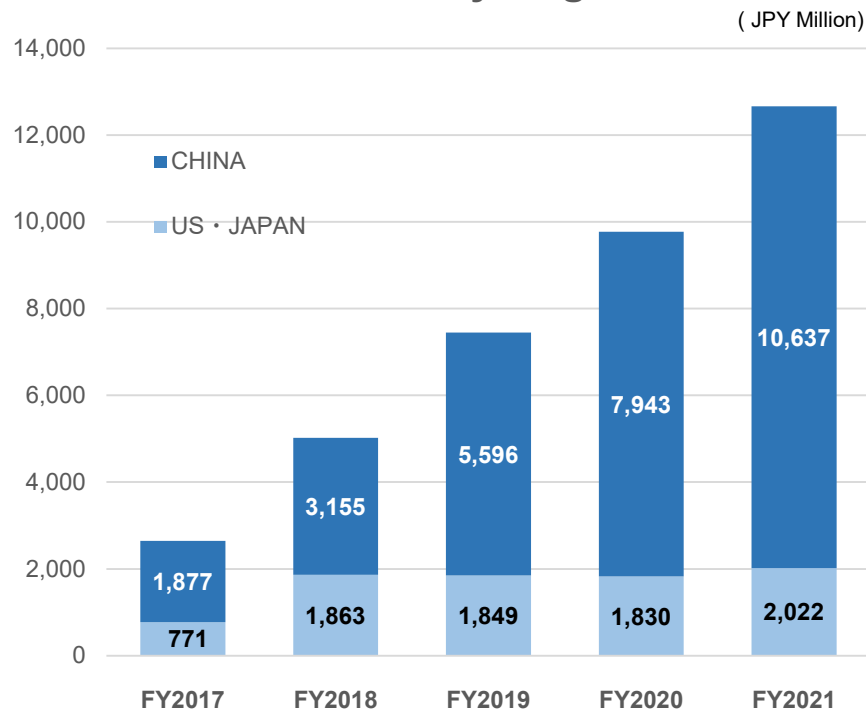
Medical Device Segment Revenue and Operating Profit



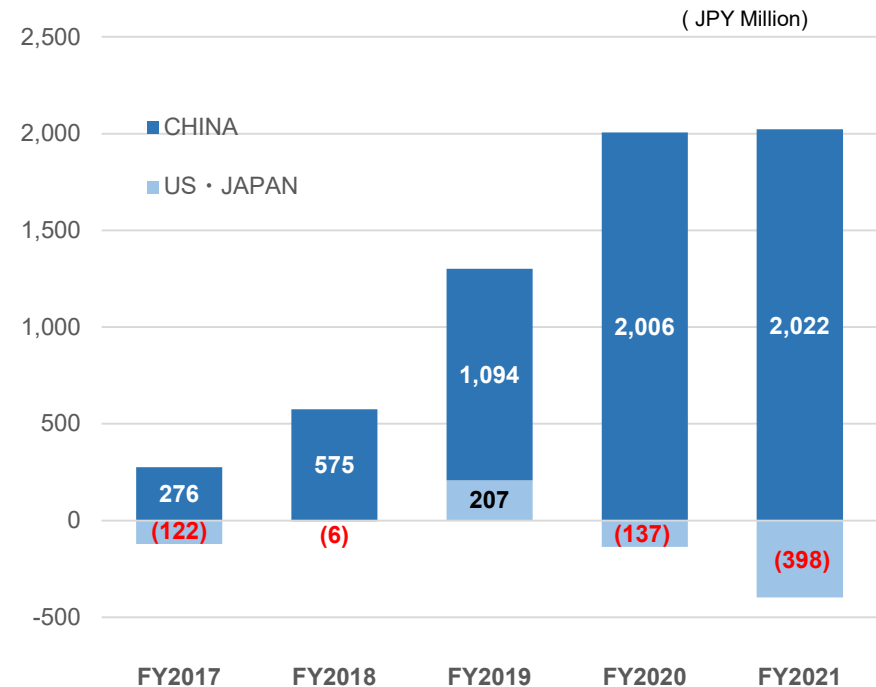
# FY2021 Reports by Geographical Regions

China is self-funded with its diversified presence; the USA is largely R&D-focused.

Revenue by Region



Operating Profit by Region



## FY2021 SG&A Expenses

Increase in SG&A primarily reflects YoY increases in headcount at Cullgen and BC. Overall, headcount grew 19% from 530 at year-end 2020 to 630 at year-end 2021

(JPY Million)

	2020 Actual	2021 Plan	2021 Actual	Change	
				2021 Act. vs 2020 Act.	2021 Act. vs 2021 Plan
<b>Japan</b>	350	481	475	125	(6)
<b>USA</b>	835	1,226	1,336	501	110
<b>Cullgen</b>	237	639	696	459	57
<b>BAB</b>	537	517	562	25	45
<b>Others</b>	61	70	78	17	8
<b>China</b>	3,995	5,522	6,148	2,153	626
<b>BC</b>	3,685	5,130	5,708	2,023	578
<b>SG</b>	53	39	51	(2)	12
<b>Cullgen Shanghai</b>	58	92	102	44	10
<b>Others</b>	199	261	287	88	26
<b>Total</b>	<b>5,180</b>	<b>7,229</b>	<b>7,958</b>	<b>2,778</b>	<b>729</b>

BAB : Berkeley Advanced Biomaterials LLC BC : Beijing Continent Pharmaceutical Co., Ltd SG : Shanghai Genomics

## FY2021 R&D Expenses

R&D expenses increased in both the USA and China. BC's grew according to plan, while Cullgen was under plan, but up 82% over 2020

(JPY Million)

	2020 Actual	2021 Plan	2021 Actual	Change	
				2021 Act. vs 2020 Act.	2021 Act. vs 2021 Plan
Japan	17	15	0	(17)	(15)
USA	233	677	330	97	(347)
Cullgen	178	594	322	144	(272)
BAB	0	0	0	0	0
Others	55	83	8	(47)	(75)
China	993	1,576	1,685	692	109
BC	483	844	891	408	47
SG	97	29	70	(27)	41
Cullgen Shanghai	380	698	719	339	22
Others	33	5	5	(29)	0
<b>Total</b>	<b>1,243</b>	<b>2,268</b>	<b>2,015</b>	<b>772</b>	<b>(253)</b>

BAB : Berkeley Advanced Biomaterials LLC    BC : Beijing Continent Pharmaceutical Co., Ltd    SG : Shanghai Genomics

# Momentum continues – Bringing New Hope to Patients

- ❑ BAU (Business as Usual) 5-year CAGR 57%
- ❑ Normalization of results for non-recurring and non-cash costs produces a very different PnL and insight into the business.
- ❑ Decomposition of IFRS-reported figures for impacts of deconsolidation and/or other non-economic value charges brings to the surface values inherent in GNI Group's business.

(JPY Million)

IFRS-Based	Revenue	Operating profit (Loss)	Profit before tax (loss)	Profit after tax(loss)	Profit (loss) attributable to company owners
FY2023 Preliminary Plan	19,457	2,836	1,794	494	1,439
FY2022 Budget	16,334	1,815	988	36	961
FY 2021 Actual	12,690	1,624	1,107	55	1,066
FY2020 Actual	9,773	1,869	1,805	1,365	1,258
FY2019 Actual	7,446	1,302	1,197	629	181
FY2018 Actual	5,018	568	364	192	(200)
FY2017 Actual	2,648	154	137	28	(175)
FY2016 Actual	1,306	(276)	(385)	(465)	(513)

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