

The following information was originally prepared and published by GNI Group Ltd. in Japanese as it contains timely disclosure materials to be submitted to the Tokyo Stock Exchange. 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. The following information was prepared in accordance with International Financial Reporting Standards (“IFRS”).



Consolidated Financial Results for FY2022 (IFRS)

February 15, 2023

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 Annual General Shareholder Meeting Date March 30, 2023
 Annual financial report (Yuho) disclosure date: March 31, 2023
 Scheduled dividend payment commencement date: -
 Supplementary materials prepared for financial results: Yes
 Financial result briefing meeting: Yes (For institutional investors and analysts)

(Amounts of less than one million yen are rounded down)

1. Consolidated Financial Results for FY2022 (January to December)

(1) Consolidated Operating Results

(Percentages are shown as year-on-year changes)

	Revenue		Operating profit		Profit before tax		Profit for the year		Profit attributable to owners of the parent		Total comprehensive income for the year	
	Million yen	%	Million yen	%	Million yen	%	Million yen	%	Million yen	%	Million yen	%
FY2022	17,418	37.3	1,377	(15.2)	767	(30.6)	(800)	-	456	(57.2)	256	(83.8)
FY2021	12,690	29.8	1,624	(13.1)	1,107	(38.7)	55	(96.0)	1,066	(15.3)	1,577	61.2

	Basic earnings per share	Diluted earnings per share	Ratio of profit for the year to equity attributable to owners of the parent	Ratio of profit before tax to total assets	Ratio of operating profit to revenue
	Yen	Yen	%	%	%
FY2022	9.61	9.52	2.3	2.4	7.9
FY2021	22.72	22.08	7.1	4.1	12.8

(2) Consolidated Financial Position

	Total assets	Total equity	Total equity attributable to owners of the parent	Ratio of total equity attributable to owners of the parent to total assets	Total equity attributable to owners of the parent per share
	Million yen	Million yen	Million yen	%	Yen
FY2022 end	33,906	19,879	21,038	62.0	443.03
FY2021 end	30,296	19,266	18,860	62.3	397.38

(3) Consolidated Cash Flows

	Cash flows from operating activities	Cash flows from investing activities	Cash flows from financing activities	Cash and cash equivalents as of the end of period
	Million yen	Million yen	Million yen	Million yen
FY2022	393	(4,116)	(646)	11,049
FY2021	552	(260)	2,853	14,352

2. Dividends

	Dividends per share					Total amount of dividends	Dividend payout ratio (consolidated)	Ratio of dividend to total equity attributable to owners of the parent (consolidated)
	Q1-end	Q2-end	Q3-end	Year-End	Total			
	Yen	Yen	Yen	Yen	Yen	Million yen	%	%
FY2021	-	-	-	0.00	0.00	-	-	-
FY2022	-	-	-	0.00	0.00	-	-	-
FY2023 (Forecast)	-	-	-	0.00	0.00		-	

3. Consolidated Earnings Forecasts for FY2023 (January to December)

(Percentages are shown as year-on-year changes)

	Revenue		Operating profit		Profit before tax		Profit for the year		Profit attributable to owners of the parent		Basic earnings per share
	Million yen	%	Million yen	%	Million yen	%	Million yen	%	Million yen	%	Yen
FY2023	17,100 ~ 20,900	(1.8) ~ 20.0	700 ~ 1,400	(49.2) ~ 1.6	(100) ~ 200	(113.0) ~ (74.0)	(500) ~ 0	n/a	1,100 ~ 1,400	141.1 ~ 206.9	22.30 ~ 33.41

Note: Amendment from the forecast most recently published: No

Notes:

- (1) Changes in Significant Subsidiaries during the Period under Review: Yes
(Changes in specified subsidiaries resulting in a change in the scope of consolidation)
New: Micren Healthcare Co., Ltd.
Excluded: N.A.
- (2) Changes in Accounting Policies and Changes in Accounting Estimates
 - ① Changes in accounting policies that are required under IFRS: N.A.
 - ② Changes in accounting policies other than ①: N.A.
 - ③ Changes in accounting estimates: N.A.
- (3) Number of Shares Issued (Common Stock)

① Number of shares issued as of the end of the period (including treasury stock)	FY2022	47,487,843 shares	FY2021	47,462,943 shares
② Number of treasury stock as of the end of the period	FY2022	1,391 shares	FY2021	1,313 shares
③ Average number of shares for the period	FY2022	47,473,964 shares	FY2021	46,924,021 shares

* This consolidated financial report is not subject to audit procedures by certified public accountants or an auditing firm.

* Explanation Concerning the Proper Use of Financial Results Forecasts and Other Relevant Specific Items

Forward-looking statements including earnings forecasts contained in this report are based on currently available information and management's assumptions and beliefs regarding uncertainties that may impact future earnings forecasts. The Company cautions readers that actual results may differ materially from forecasts due to a variety of factors. For the assumptions that underpin financial results forecasts as well as other related items, please refer to "1. (5) Outlook for the fiscal year ending December 31, 2023."

The Group is planning to conduct a corporate presentation meeting for institutional investors and analysts on February 17, 2023. Briefing materials used at that session will be posted on the Group's website.

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1. Analysis of Operating Results and Financial Position

(1) Analysis of operating results

GNI Group (“we” or “the Group”), consists of GNI Group Ltd. (“the Company” or “Tokyo Headquarter”) in Japan and its subsidiaries, most notably two major revenue / profit contributing subsidiaries (Beijing Continent Pharmaceutical Co., Ltd. [“Continent”] and Berkeley Advanced Biomaterials LLC [“BAB”]). Additionally, the Group holds two major entities that are cost centers by design: one is dedicated to oncology-related R&D investment spending Cullgen, Inc. [“Cullgen”]; the other entity is the Tokyo Headquarter which provides essential group-wide corporate planning, accounting, banking and administrative services as a listed member of the TSE's Growth board. Several smaller subsidiaries also provide the Group with strategic growth optionality. In the Pharmaceutical Segment these are Shanghai Ruifu International Trade Co., Ltd. (“Reef”), Shanghai Genomics, Inc. (“SG”), Shanghai Genomics Technology, Ltd. (“SGT”). In the Medical Device Segment in addition to BAB, we invested in Q4 2022 and took control of 60% of a regulatory and Designated Marketing Authorization Holder (“DMAH”) consulting specialist business whose customers are offshore medical device product manufacturers seeking access to Japan. Please note that the Group’s consolidated financials are heavily influenced by income / loss from investments, tax, currency-exchange rate, and non-cash items. The Company’s ownership percentage in each subsidiary may also have a significant impact on profit attributable to owners of the parent.

In 2022, the Group’s revenue in the **Pharmaceutical Segment** grew even while facing the most challenging pandemic conditions in modern China history, although the pace was slower than we expected at the beginning of the year. The group’s revenue from the Pharmaceutical Segment was JPY 14.9 billion, up 37.6% compared with 2021, including RMB 688.6 million from CONTINENT, up 18.8% from 2021. Continent’s Operating and Net Profits reached RMB 189.5 and 151.6 million, respectively, the highest in history.

Higher operating profit of Continent is partially offset by many factors: one-time write-off of RMB 20.4 million (JPY 395.3 million) of IPO listing expenses incurred before we decided not to pursue HKEX listing further but rather to seek the transactions with Catalyst Biosciences, Inc. (“CBIO”) in the U.S. (please refer to the disclosure on December 27, 2022); significantly increased R&D spending at Cullgen for targeted protein degradation (“TPD”) drug platform with multiple IND¹⁾-enabling studies to build a future pipeline in cancer and inflammatory diseases; and slightly elevated selling expenses due to frequent lockdowns during COVID-19 pandemics in China. In addition, due to the challenges which buffeted the global biotech sector in 2022, the value of our shares in private company CellCarta (formerly Reveal) was reduced by 51.3% to USD 2.4 million after a third-party appraisal, and the value of our shares in public company, Societal, formerly known as Recro Pharma, was reduced by 12.9% to USD 251.4 thousand. As a result, the segment profit of the entire Pharmaceutical Segment (including Continent, Cullgen, Reef, SGT, SG) was JPY 431 million, down 56.1% compared with 2021. At Continent alone without the one-time expenses of the lapsed IPO, its Operating Profit would have been RMB 209 million.

1): Investigational New Drug. Request for authorization from the authority to administer a clinical trial of a drug

Our **Medical Device Segment** has also resumed steady growth in the U.S. and achieved a record revenue of JPY 2.5 billion, up 31.4% compared with 2021. High inflation rate in the U.S. slightly impacted the segment profit of the Medical Device Segment, which was JPY 946 million in 2022, up 47.5% from 2021. We expect this segment’s revenue will also continue to grow in 2023.

Finally, additional spending was recorded at the Group’s headquarter in Japan due to additional spending on professional services for M&A activities and enhancement of management team by hiring more executives / managers.

Taken together, although the Group’s consolidated revenue for the entire fiscal year 2022 was JPY 17.4 billion, up 37.3% YoY reaching the record high in the Group’s history, the Group’s full-year consolidated operating profit came out to be JPY 1.3 billion, down 15.2% YoY. The Group’s consolidated full-year profit before tax was JPY 767 million, down 30.6% YoY primarily due to non-cash accrual of the interest expenses of USD 6.4 million related to Cullgen’s past financing as the financial expenses. As a result of discussions with the auditor, our assignment of F351 IP ex-China to CBIO as a part of our reverse merger generated Other Income of JPY 432.2 million based on the value of our initial ownership of 6,266,521 common shares of CBIO under IFRS at December end, 2022. We note that, on the other hand, our tax advisors have opined that USD 35 million in economic value of the transaction, agreed upon by both the buyer and the seller, will be considered as income for tax purposes in Japan.

Recently, the biotech sectors in the global stock markets have started to warm up. We will watch for signs of improvement because these factors will significantly impact our consolidated full-year profit in 2023.

Finally, the Group’s consolidated full-year loss after tax was JPY 800 million. Income tax expense was JPY 1.5 billion yen, which was

high compared to profit before tax of JPY 767 million. The reason is that while the income generated by Continent, BAB and other profitable subsidiaries are taxed respectively, the loss incurred by cost centers like Cullgen and Tokyo Headquarter cannot be recognized as deferred tax assets because taxable income is not anticipated in the foreseeable future in those entities.

The Group's full-year consolidated profit attributable to owners of the parent was JPY 456 million, down 57.2% YoY. Profit attributable to owners of the parent is higher than profit / loss after tax primarily because the above loss is distributed to the other owners of Cullgen, and only the loss that belongs to the Company is booked in our profit attributable to owners of the parent. Please note that the Group's holding is higher in profitable subsidiaries such as Continent (56.0%) and BAB (100%) than in R&D-heavy Cullgen (28.3%) in 2022.

Beijing Continent Pharmaceutical Co., Ltd., just like all the other companies operating in China, has been negatively impacted by the multi-month lockdowns in many places in the country and followed by a rapid spread of infections in December after the zero-COVID policy is lifted in China. However, Continent achieved 19% YoY growth in RMB terms, which is a marvelous achievement. Net profit reached RMB 151.6 million in 2022. COVID-19 impacts throughout China have caused Continent to delay by three months the clinical trial for F351 vs the original target of patient enrollment completion in the middle of 2023. Continent is carefully monitoring the pandemic situation and devising a measure, such as increasing the test sites, to catch up after the turmoil calms down. Please note that Continent has terminated its plan to list on the HKEX for the foreseeable future. Consequently, it has written off the accumulated IPO expenses of RMB 17.0 million that had been capitalized.

Berkeley Advanced Biomaterials LLC grew steadily in the US during 2022. Its revenue for the whole year grew by 10.4% YoY in local currency terms and has been a steady source of cash distributions to GNI USA. For BAB, we see 2023 as an important year to embark upon business expansion of its bone replacement raw material for usage in various aesthetics applications internationally. The Group has also decided to invest USD 1.3 million into **Shanghai Ruixing Medical Equipment Co., Ltd. ("Ruixing")** in 2022, specializing in derma filler, utilizing the similar bone filler platform. We are excited to pursue a wider use of the biomaterial platform in 2023. Ruixing is planning to change its name to **Osderma Medical** later this year.

In Japan, as announced in October 7 and December 1, 2022, the Company further expanded Medical Device Segment by investing JPY 360 million for a 60% controlling position in the regulatory consulting firm, **Micren Healthcare Co., Ltd. ("Micren")**, formerly owned 100% by a subsidiary of EPS Holdings, Inc, EP Mediate Co., Ltd. With 10 staffs and approximately 30 clients, Micren is a Designated Marketing Authorization Holder (DMAH) and in-country caretaker service provider for foreign Medical Device companies seeking to access the Japan market. Micren's financial results will be included into our consolidated financial results starting 2023.

Cullgen, Inc represents the Group's investment into the cutting-edge drug discovery platform of targeted protein degradation (TPD). We believe it is the single most important investment for the Group's long-term future. Cullgen filed their first IND for a cancer drug candidate using a TRK degrader in 2022 when the COVID-19 lockdown in Shanghai was at its peak. The subject enrollment of Phase I clinical trial for TRK degrader is expected in Q1 2023. Multiple other IND-enabling programs are also progressing. In 2022, R&D spending increased by 13.6% in the U.S. and 33.2% in China, respectively, in local currency terms. Please note that, due to JPY depreciation to USD, R&D expense increase coming from Cullgen has a higher impact in JPY on the Group's consolidated financial results. To generate a return on our investment in Cullgen, we will seek listing of Cullgen in the future.

As disclosed on December 27, 2022, the Group has entered into a series of strategic transactions with CBIO, a Nasdaq-listed biotechnology company. Utilizing CBIO as a platform, this corporate event forms a base for secular advancement of our fibrosis drug development in the USA while leveraging the Group's well-established clinical research and drug development platform in China. For more information about the CBIO reverse merger, please refer to our disclosure on December 27, 2022 and subsequent FAQ's published on December 30, 2022 and January 18, 2023

The exchange rates used for the Group's fiscal year 2022 consolidation are as follows:

Statements of financial position	Statements of income
1 USD = 132.70 JPY	1 USD = 130.77 JPY
1 RMB = 19.01 JPY	1 RMB = 19.38 JPY

① **Operating results by segment**
Pharmaceutical Segment

Despite all the difficulties in the market, the revenue from the Group's main subsidiary Continent achieved growth from its flagship drug product ETUARY® in China on a local currency basis. In JPY terms, the Pharmaceutical Segment as a whole had JPY 14.9 billion in revenue, up 37.6% YoY. The segment profit was JPY 431 million, down 56.1% YoY. The decrease in profit was mainly due to increased R&D and sales and marketing expenses and one-time expenses related to CBIO transaction and write-off of Continent's IPO preparation costs.

Medical Device Segment

Our Medical Device Segment performed well; their revenue for the period totaled JPY 2.5 billion, up 31.4% YoY, back at a healthy growth rate after COVID-19 pandemic. Segment profit was JPY 946 million, up 47.5% YoY.

② Selling, General and Administrative Expenses; Research and Development Expenses

Thousand yen

	FY2021	FY2022	Difference
Selling, general and administrative expenses	(7,958,654)	(10,965,656)	(3,007,001)
Personnel expenses	(2,983,245)	(3,636,074)	(652,829)
Research and development expenses	(2,015,875)	(2,545,455)	(529,580)

Note: Personnel expenses exclude Board member emoluments; actual salaries paid only.

Selling, general and administrative (SG&A) expenses in JPY terms for 2022 were JPY 10.9 billion, up 37.8% YoY. The increase in SG&A expenses come mainly from increased sales and marketing expenses, legal expenses related to CBIO transaction, write-offs of Continent's IPO preparation costs and of investments in CellCarta (formerly Reveal) and Societal (formerly Recro Pharma), and increased expenses in the Tokyo Headquarter from professional service fees regarding various investments and M&A transactions.

Research and Development expenses in JPY terms for 2022 were JPY 2.5 billion, up 26.3% YoY from Cullgen in particular as they prepare for coming clinical trials. Continent's R&D expenditure declined YoY mainly due to COVID-19 pandemic.

③ Finance Income and Finance Costs

Thousand yen

	FY2021	FY2022	Difference
Finance income	129,960	259,835	129,875
Finance costs	(647,898)	(869,887)	(221,989)

Finance income

In 2022, the Group recorded finance income of JPY 259 million, up 99.9% YoY caused mainly by currency translation from depreciating Japanese yen.

Finance costs

In 2022, the Group recorded finance costs of JPY 869 million, up 34.3% YoY. These finance costs come from non-cash accrual of interest expenses related to financing activities at Cullgen.

(2) Analysis of financial position

Summary of Consolidated Financial Position

Thousand yen

	As of December 31, 2021	As of December 31, 2022	Difference
Total assets	30,296,980	33,906,981	3,610,001
Total liabilities	11,030,734	14,027,696	2,996,962
Total equity	19,266,246	19,879,284	613,038

Total assets

As of 2022 end, the total assets stood at JPY 33.9 billion, a 11.9% increase compared to the previous fiscal year end. This increase primarily comes from acquisition of property, plant, and equipment; increase in R&D expense capitalization; increase in goodwill due to weaker JPY; and increase in working capital due to increasing business activities. In addition, long-term bank deposits purchased in China are included in these figures.

Total liabilities

As of 2022 end, the total liabilities stood at JPY 14.0 billion, a 27.2% increase compared to the previous fiscal year end. This increase was primarily due to additional non-cash accrual of interest expenses related to Cullgen's funding.

Total equity

As of 2022 end, the total equity stood at JPY19.8 billion, a 3.2% increase compared to the previous fiscal year end. The increase was mainly due to the increase in retained earnings and exchange differences on translation of foreign operations.

(3) Analysis of cash flows

Summary of Consolidated Cash Flows

Thousand yen

	FY2021	FY2022	Difference
Cash flows from operating activities	552,268	393,320	(158,947)
Cash flows from investing activities	(260,639)	(4,116,163)	(3,855,523)
Cash flows from financing activities	2,853,211	(646,327)	(3,499,538)

Cash flows from operating activities

The cash flow from operating activities came to JPY 393 million in 2022, a 28.8% decrease YoY. The main drivers are increase in marketing and R&D expenses as well as corporate tax payments at Continent due to their increased sales.

Cash flows from investing activities

The cash flow from investing activities came to negative JPY 4.1 billion in 2022, a 1,479.3% YoY increase. The major sources of the increase are the acquisition of fixed and non-tangible assets and the purchase of long-term deposits in Continent.

Cash flows from financing activities

The cash flow from financing activities came to negative JPY 646 million in 2022 vs positive JPY 2.8 billion in 2021. The Group engaged in multiple fund-raising events in the first half of 2021, while there has been no such financing activity in 2022.

(4) Research and development activities

[Research Activities]

The Group's drug discovery activities are led by Cullgen, with the objective of developing innovative new chemical entities (NCEs) for the novel treatment of diseases, utilizing its drug discovery platform uSMITE™ (ubiquitin-mediated, small molecule induced target elimination). Cullgen continues to make steady progress with its therapeutic protein degrader pipeline, with multiple new degradation agents including enzyme and non-enzyme protein that target cancer, pain, and autoimmune indications. Cullgen's novel E3 ligand development program is the core technology that is a key to the future of targeted protein degradation and aims to develop NCEs that reduce toxicity; alleviate drug resistance; provide tissue, tumor, and subcellular compartment selectivity; and expand the substrate spectrum.

[Development Activities]

■ **ETUARY®** [Chinese: 艾思瑞®, (Generic name: Pirfenidone)] by Continent

Diabetic Kidney Disease (DKD)

The third ETUARY® indication is for DKD, a chronic kidney disease caused by type I or type II diabetes. In China, more than 130 million people suffer from diabetes as of 2021, and about 23% of which suffer from Type I or Type II diabetes that can lead to renal dysfunction. Continent has submitted the application for Type 2 meeting with China's CDE (Center for Drug Evaluation) to determine the regulatory path for the next phase of clinical trials. Beijing Continent has completed Phase I clinical studies, and we are discussing the next steps with the Chinese CDE based on the results.

Connective Tissue Disease Associated Interstitial Lung Disease (SSc-ILD and DM-ILD)

In September 2016, Continent received NMPA approval for the fourth ETUARY® indication for the treatment of SSc-ILD and DM-ILD. This IND approval authorized Continent to proceed directly into Phase III clinical trial for two indications: systemic sclerosis SSc-ILD and dermatomyositis DM-ILD. In June 2018, the first patient was enrolled for each of the Phase III clinical trials for the treatment of SSc-ILD and DM-ILD, with randomized, double-blind, placebo-controlled, 52-week clinical studies. A total of 144 and 152 subjects are scheduled to be enrolled for SSc-ILD and DM-ILD trials, respectively. The spread of a new coronavirus in China is having an impact on the clinical trials for CTD-ILD and caused some delay in the enrollment of subjects.

Pneumoconiosis (PD): F647

In May 2019, Continent received an approval for IND from NMPA on the fifth indication of ETUARY®: pneumoconiosis, a dust-related chronic lung disease that causes inflammation and scarring (fibrosis) to develop in the lungs. Continent received approval from the Ethics Committee in January 2022 to initiate Phase III clinical trial of ETUARY® for the indication of pneumoconiosis, and Phase III trial began in June 2022. Although subject enrollment is progressing well through the second half of 2022, we are closely monitoring the impact of the subsequent spread of the novel coronavirus in China.

■ **F351 (for Liver Fibrosis) (Generic Name: Hydronidone) by Continent**

F351 (Generic name: Hydronidone) is a therapeutic drug for the treatment of liver fibrosis, represents a key candidate in Continent's drug portfolio and a significant part of its strategy to expand its clinical development activities into other major global pharmaceutical markets. F351 is an NCE derivation of ETUARY®, which inhibits hepatic stellate cell proliferation and the TGF-β signaling pathway, both of which play major roles in the fibrosis of internal organs.

Continent holds the rights for F351 in China, and those in other regions including Japan, Australia, Canada, the US, and Europe were sold to CBIO. (For more information, please refer to our disclosure on December 27, 2022 and subsequent FAQ's published on December 30, 2022 and January 18, 2023.)

In August 2020, the Group announced positive results from the initial analysis of the China Phase II clinical trial of F351. The trial was a randomized, double-blind, placebo-controlled, multi-center, dose escalation study assessing the safety and efficacy of F351 for Hepatic Fibrosis in Chronic Viral Hepatitis B patients in China. The study met its primary endpoint of a statistically significant improvement in the liver fibrosis score over the 52-week treatment versus the placebo.

After consultation with China's Center for Drug Evaluation (CDE), F351 was designated as a Breakthrough Drug for Liver Fibrosis in March 2021 by NMPA. This key designation enables Continent to consult with the CDE on a preferential basis, which can prioritize its clinical trials. On July 29, 2021, F351 received Phase III clinical trial approval and on January 17, 2022, the first patient was enrolled in its trial in China, as the Group disclosed in January 2022. Although progress was steady until Q3 2022, subject enrollment was slightly behind schedule due to the outbreak of COVID-19 in China near the end of 2022.

Regarding F351's Phase II clinical trial in the US for NASH (non-alcoholic steatohepatitis, an advanced form of non-alcoholic fatty liver disease) induced liver fibrosis. Please refer to the "GNI Group and Catalyst Biosciences Signed Agreements to Advance Liver Fibrosis Drug Development" disclosed on December 27, 2022.

■F573 (for Acute liver failure and Acute on chronic liver failure [ACLF]) by Continent

Continent's third major new drug candidate following F351 is F573, a di-peptide compound that has the potential to inhibit caspases. It is an important compound that is related to apoptosis and inflammation frequently related to Acute Liver Failure (ALF) and Acute-on-Chronic Liver Failure (ACLF). The first dosing of its Phase I clinical trial was announced on January 20, 2022, and Phase I trial has made a good progress. Continent is preparing for Phase II clinical trial; however the launch of trial has been delayed due to the spread of COVID-19 in China at the end of 2022.

■CG001419 (TRK degrading agent) by Cullgen

The Group disclosed on August 9th, 2022 that "China NMPA has approved GNI Group's Subsidiary Cullgen's IND for TRK Degrader Clinical Trial". Cullgen received an IND (Investigational New Drug) approval from China's NMPA (National Medical Products Administration) for CG001419, a TRK degrader for the treatment of solid tumors. CG001419 is a first-in-class, selective, potent oral targeted protein degrader for the treatment of neurotrophic tyrosine receptor kinase (NTRK) fusion-positive / TRK overexpression cancers, which have been identified in numerous solid tumors including non-small cell lung, breast, and pancreatic cancers. Cullgen is working closely with doctors and hospitals preparing for its Phase I clinical trial in China, although the launch of the trial has been delayed due to the spread of COVID-19 in China at the end of 2022. On the US side, Cullgen continues preparations for future clinical trials, actively engaging with US FDA (Food and Drug Administration) on pre-clinical trial discussion, which is key to smooth approvals when Cullgen officially applies for IND's in the US.

(5) Outlook for the fiscal year ending December 31, 2023

Following the late 2022 lifting of COVID-19 controls in China, we are optimistic about the Pharmaceutical Segment, in particular Continent's strong existing business from ETUARY®. Continent continues hiring, and their total staff has reached 523 by the end of 2022. The modest time delay in clinical development of F351 in 2022 is already behind Continent, but we start again to push for full enrollment of all patients in 2023.

As stated in the operating results section above, Cullgen expects to enroll the first subject of Phase I clinical trial for TRK degrader in Q1, 2023. Multiple other IND enabling programs are also progressing, and Cullgen will continue enhancing its drug pipeline and exploring business opportunities utilizing their proprietary TPD technology platform uSMITE™. We will continue to invest into TPD technology because we believe it represents a breakthrough in drug discovery and has already generated strong interest among global pharmaceutical companies. If Cullgen continues to grow and attract additional sizable financing from global private equity funds, we may need to de-consolidate Cullgen, which will result in significant upward adjustment of the Group's consolidated financial numbers.

In Medical Device Segment (biomaterials business), the Group also expects BAB's main business in the U.S. to continue growing steadily, generating healthy flow of cash for the Group. We aim to make 2023 the start of expansion into aesthetics applications first in the China marketplace with additional investments into this field. We believe the Medical Device Segment will eventually will grow into a size that constitutes about 40% of the Group's profit in the coming years..

For 2023, the impact of CBIO to the Group's consolidated financials is expected to be limited.

Although we are optimistic that revenue of 2023 will reach a new high, we need to pay attention to a wide range of recent macroeconomic and geopolitical developments worldwide, including volatile currency exchange markets and supply chain challenges. Due to these challenges, financial forecasting has become ever more challenging. For this reason, we have published our preliminary PnL forecast figures using ranges. The assumed exchange rates for the consolidated earnings forecast are US\$1 = ¥130.77 and RMB1 = ¥19.38.

2. Basic Policy on the Selection of Accounting Standards

GNI Group applies International Financial Reporting Standards [IFRS].

3. Consolidated Financial Statements and Notes

(1) Consolidated statements of financial position

Thousand yen

	FY2021 (As of Dec 31, 2021)	FY2022 (As of Dec 31, 2022)
Assets		
Non-current assets		
Property, plant and equipment	2,943,602	3,951,217
Right-of-use assets	865,959	755,167
Goodwill	5,020,290	6,047,721
Other intangible assets	2,147,671	2,928,800
Investments accounted for using the equity method	-	622,476
Deferred income tax assets	180,940	184,171
Other financial assets	951,513	2,270,162
Total non-current assets	<u>12,109,978</u>	<u>16,759,717</u>
Current assets		
Inventories	1,382,702	1,693,412
Trade and other receivables	1,885,101	3,122,463
Other financial assets	4,743	196,543
Other current assets	562,320	1,085,535
Cash and cash equivalents	14,352,133	11,049,310
Total current assets	<u>18,187,002</u>	<u>17,147,264</u>
Total assets	<u><u>30,296,980</u></u>	<u><u>33,906,981</u></u>
Liabilities and equity		
Non-current liabilities		
Lease liabilities	280,724	157,744
Deferred income tax liabilities	501,194	478,474
Other financial liabilities	7,539,814	9,706,958
Other non-current liabilities	165,840	181,027
Total non-current liabilities	<u>8,487,574</u>	<u>10,524,204</u>
Current liabilities		
Trade and other payables	371,138	949,612
Borrowings	700,000	200,000
Lease liabilities	145,662	179,611
Current tax payable	542,019	1,179,254
Other financial liabilities	6,918	7,225
Other current liabilities	777,420	987,788
Total current liabilities	<u>2,543,159</u>	<u>3,503,492</u>
Total liabilities	<u>11,030,734</u>	<u>14,027,696</u>
Equity		
Capital stock	10,884,332	10,893,070
Capital surplus	6,224,649	6,233,386
Treasury stock	(645)	(756)
Retained earnings (loss)	307,535	763,683
Other components of equity	1,444,437	3,148,625
Total equity attributable to owners of the parent	<u>18,860,309</u>	<u>21,038,009</u>
Not-controlling interests	405,936	(1,158,724)
Total equity	<u>19,266,246</u>	<u>19,879,284</u>
Total equity and liabilities	<u><u>30,296,980</u></u>	<u><u>33,906,981</u></u>

(2) Consolidated statements of income and consolidated statements of comprehensive income

Consolidated statements of income

Thousand yen

	FY2021 (Jan 1, 2021 to Dec 31, 2021)	FY2022 (Jan 1, 2022 to Dec 31, 2022)
Revenue	12,690,246	17,418,966
Cost of sales	(1,600,498)	(2,674,409)
Gross profit	<u>11,089,748</u>	<u>14,744,556</u>
Selling, general and administrative expenses	(7,958,654)	(10,965,656)
Research and development expenses	(2,015,875)	(2,545,455)
Other income	662,772	664,743
Other expenses	(153,041)	(520,248)
Operating profit	<u>1,624,948</u>	<u>1,377,939</u>
Finance income	129,960	259,835
Finance costs	(647,898)	(869,887)
Profit before tax	<u>1,107,010</u>	<u>767,887</u>
Income tax expense	(1,051,767)	(1,568,817)
Profit (loss) for the year	<u><u>55,242</u></u>	<u><u>(800,930)</u></u>
Profit (loss) attributable to:		
Owners of the parent	1,066,185	456,148
Non-controlling interests	(1,010,943)	(1,257,078)
Earnings per share		
Basic earnings per share (Yen)	22.72	9.61
Diluted earnings per share (Yen)	22.08	9.52

Consolidated statements of comprehensive income

Thousand yen

	FY2021 (Jan 1, 2021 to Dec 31, 2021)	FY2022 (Jan 1, 2022 to Dec 31, 2022)
Profit (loss) for the year	55,242	(800,930)
Other comprehensive income		
Items that may be reclassified to profit or loss, net of tax		
Exchange differences on translation of foreign operations	1,522,252	1,056,942
Total other comprehensive income (loss)	1,522,252	1,056,942
Total comprehensive income for the year	1,577,495	256,012
Total comprehensive income (loss) for the year attributable to:		
Owners of the parent	2,378,240	1,879,589
Non-controlling interests	(800,744)	(1,623,576)

(3) Consolidated statement of changes in equity
 FY2021 (from Jan 1, 2021 to Dec 31, 2021)

Thousand yen

	Attributable to owners of the parent							Total
	Capital stock	Capital surplus	Treasury stock	Retained profit (loss)	Other components of equity			
					Subscription rights to shares	Exchange differences on translation of foreign operations		
Balance as of Jan 1, 2021	8,268,472	3,591,101	(472)	(608,019)	163,354	(414,404)	(251,049)	
Profit (loss) for the year	-	-	-	1,066,185	-	-	-	
Other comprehensive income	-	-	-	-	-	1,312,054	1,312,054	
Total comprehensive profit for the year	-	-	-	1,066,185	-	1,312,054	1,312,054	
Change in the interests in its controlled subsidiary	-	(3,049,137)	-	-	-	(53,774)	(53,774)	
Change in scope of consolidation	-	-	-	-	-	-	-	
Payment of distributions	-	-	-	(150,838)	-	-	-	
Issuance of new shares	2,615,859	2,615,859	-	-	(12,930)	-	(12,930)	
Share-based compensation transaction	-	-	-	-	345,204	-	345,204	
Issuance of new subscription rights to shares	-	-	-	-	51,537	-	51,537	
Issuance cost of new shares	-	(18,772)	-	-	-	-	-	
Issuance cost of subscription rights to shares	-	-	-	-	(3,719)	-	(3,719)	
Purchase of treasury stock	-	-	(172)	-	-	-	-	
Put option for non-controlling interest	-	3,085,598	-	-	-	57,116	57,116	
Others	-	-	-	207	-	-	-	
Total transactions with owners	2,615,859	2,633,547	(172)	(150,631)	380,090	3,342	383,433	
Balance as of Dec 31, 2021	10,884,332	6,224,649	(645)	307,535	543,445	900,992	1,444,437	

	Total attributable to owners of the parent	Non-controlling interests	Total equity
Balance as of Jan 1, 2021	11,000,032	1,769,072	12,769,104
Profit (loss) for the year	1,066,185	(1,010,943)	55,242
Other comprehensive income	1,312,054	210,198	1,522,252
Total comprehensive profit (loss) for the year	2,378,240	(800,744)	1,577,495
Change in the interests in its controlled subsidiary	(3,102,911)	(794,760)	(3,897,672)
Change in scope of consolidation	-	(523,254)	(523,254)
Payment of distributions	(150,838)	-	(150,838)
Issuance of new shares	5,218,789	-	5,218,789
Share-based compensation transaction	345,204	-	345,204
Issuance of new subscription rights to shares	51,537	-	51,537
Issuance cost of new shares	(18,772)	-	(18,772)
Issuance cost of subscription rights to shares	(3,719)	-	(3,719)
Purchase of treasury stock	(172)	-	(172)
Put option for non-controlling interest	3,142,714	755,624	3,898,338
Others	207	-	207
Total transactions with owners	5,482,036	(562,390)	4,919,646
Balance as of Dec 31, 2021	18,860,309	405,936	19,266,246

FY2022 (Jan 1, 2022 to Dec 31, 2022)

Thousand yen

	Attributable to owners of the parent						
	Capital stock	Capital surplus	Treasury stock	Retained profit(loss)	Other components of equity		Total
					Subscription rights to shares	Exch. diff on translation of foreign operations	
Balance at Jan 1, 2022	10,884,332	6,224,649	(645)	307,535	543,445	900,992	1,444,437
Profit (loss) for the year	-	-	-	456,148	-	-	-
Other comprehensive income	-	-	-	-	-	1,423,440	1,423,440
Total comprehensive income	-	-	-	456,148	-	1,423,440	1,423,440
Change in scope of consolidation	-	-	-	-	-	-	-
Issuance of new shares	8,737	8,737	-	-	-	-	-
Stock-based compensation transactions	-	-	-	-	276,230	-	276,230
Issuance of new subscription rights to shares	-	-	-	-	6,409	-	6,409
Issuance cost of subscription rights to shares	-	-	-	-	(1,892)	-	(1,892)
Purchase of treasury stock	-	-	(111)	-	-	-	-
Total amount of transactions with owners	8,737	8,737	(111)	-	280,746	-	280,746
Balance at Dec 31, 2022	10,893,070	6,233,386	(756)	763,683	824,192	2,324,432	3,148,625

	attributable to owners of the parent	Non-controlling interests	Total equity
	Total		
Balance as of Jan 1 2022	18,860,309	405,936	19,266,246
Profit (loss) for the year	456,148	(1,257,078)	(800,930)
Other comprehensive income (loss)	1,423,440	(366,497)	1,056,942
Total comprehensive income (loss)	1,879,589	(1,623,576)	256,012
Change in scope of consolidation	-	58,915	58,915
Issuance of new shares	17,475	-	17,475
Stock compensation transactions	276,230	-	276,230
Issuance of new subscription rights to shares	6,409	-	6,409
Issuance cost of subscription rights to shares	(1,892)	-	(1,892)
Purchase of treasury stock	(111)	-	(111)
Total amount of transactions with owners	298,110	58,915	357,025
Balance as of Dec 31 2022	21,038,009	(1,158,724)	19,879,284

(4) Consolidated statements of cash flows

Thousand yen

	FY2021 (Jan 1, 2021 to Dec 31, 2021)	FY2022 (Jan 1, 2022 to Dec 31, 2022)
Cash flows from operating activities		
Profit before tax	1,107,010	767,887
Depreciation and amortization	383,033	472,976
Decrease (increase) in accounts receivables	(318,206)	(1,092,192)
Increase (decrease) in accounts payables	(92,152)	559,902
Decrease (increase) in inventories	(308,742)	(205,446)
Increase (decrease) in bonus allowance	24,382	26,260
Finance income and finance costs	572,540	747,638
Other, net	(262,212)	188,344
Subtotal	1,105,653	1,465,371
Interest received	70,049	71,150
Interest paid	(32,695)	(27,760)
Income tax paid	(590,740)	(1,115,440)
Net cash provided by (used in) operating activities	552,268	393,320
Cash flows from investing activities		
Increase (decrease) in time deposit	-	(1,164,533)
Purchases of property, plant and equipment	(379,488)	(973,523)
Proceeds from sales of property, plant and equipment	453	-
Purchases of other intangible assets	(314,913)	(966,453)
Increase in lease and guarantee deposits	(14,187)	(266)
Decrease in lease and guarantee deposits	30	450
Proceeds from loans receivable	13,628	4,743
Purchase of investment securities	(246,319)	(589,252)
Proceeds from sales of investment securities	678,415	-
Investment to affiliated companies	-	(181,254)
Acquisition of subsidiaries with a change in scope of consolidation	-	(246,073)
Others	1,739	-
Net cash provided by (used in) investing activities	(260,639)	(4,116,163)
Cash flows from financing activities		
Increase (decrease) in short-term loans payable	20,902	(500,000)
Repayment of long-term loans payable	(800,000)	-
Proceeds from the issuance of shares	-	-
Proceeds from the issuance of shares attributable to the exercise of subscription rights to shares	1,319,377	-
Proceeds from the issuance of subscription rights to shares	86,425	6,409
Proceeds from financing by non-controlling interests	3,020,600	-
Payment of distributions to non-controlling interests	-	-
Purchase of treasury stock	(172)	(111)
Purchase of subsidiary shares resulting in the same scope of consolidation	-	-
Repayment of lease liabilities	(88,948)	(152,624)
Payment to non-controlling interests	(524,447)	-
Payment of distributions	(150,838)	-
Others	(29,686)	-
Net cash provided by (used in) financing activities	2,853,211	(646,327)
Impact of exchange rate fluctuations	884,629	1,066,346

Increase (decrease) in cash and cash equivalents	4,029,469	(3,302,823)
Cash and cash equivalents as of the beginning of the period	10,322,664	14,352,133
Cash and cash equivalents as of the end of the period	14,352,133	11,049,310

- (5) Notes to the consolidated financial statements
 (Notes related to going concern assumptions)
 Not applicable.

(Basis of preparation)

(1) Matters relating to IFRS

The Group's consolidated financial statements are prepared in accordance with International Financial Reporting Standards (IFRS) published by the International Accounting Standards Board.

Meeting the criteria of a "specified company" as defined under Article 1-2 of the Ordinance on Terminology, Forms and Preparation Methods of Consolidated Financial Statements (Ministry of Finance Ordinance No. 28, 1976), GNI Group's consolidated financial statements are prepared in accordance with Article 93 of the same.

(2) Basis of measurement

Except for the financial instruments measured at fair value, the Group's consolidated financial statements are prepared on a cost basis.

(3) Functional currency and presentation currency

The Group's consolidated financial statements are presented in Japanese yen, its functional currency. Figures of less than one thousand yen are rounded down.

(4) New standards not yet adopted

Of the newly established and revised standards and interpretations of accounting principles published by the date of approval for these consolidated financial statements, there are no standards and interpretations of accounting principles not adopted by GNI Group, which has material effect impact.

(Segment information)

(1) Reportable segments

The Group's reportable segments, from which separate financial data can be obtained, are subject to periodic review by the Board of Directors for the purpose of deciding the allocation of resources and assessing performance.

The Group has two business segments: Pharmaceutical Segment consisting of drug development, manufacturing, and sales activities as well as contracted research operations; and the Medical Device Segment consisting of development, manufacturing and sales activities.

The major products in each reportable segment are as follows.

Reportable segment	Company name	Main product
Pharmaceutical	GNI Group Ltd.; Beijing Continent Pharmaceutical Co., Ltd; Shanghai Genomics, Inc.; GNI Hong Kong Limited; GNI Tianjin Limited; Shanghai Genomics Technology, Ltd.; Cullgen (Shanghai), Inc.; GNI USA, Inc.; Cullgen Inc.; SHANGHAI RUI FU INTERNATIONAL TRADE CO., LTD.	ETUARY [®] , drug discovery and development, reagents etc.
Medical Device	Berkeley Advanced Biomaterials LLC, Micren Healthcare Co., Ltd.	Orthobiologics material, Designated Marketing Authorization Holder (DMAH) and in-country caretaker service

(2) Reportable segment revenue and profit

Information about the Company's reportable segments is as follows.

FY2021 (Jan 1, 2021 to Dec 31, 2021)

Thousand yen

	Reportable segment			Adjustments	Consolidated
	Pharmaceutical	Medical Device	Total		
Revenue					
(1) Revenue to outside customers	10,895,082	1,795,164	12,690,246	-	12,690,246
(2) Intra-segment revenue and transfers	-	123,958	123,958	(123,958)	-
Total	10,895,082	1,919,122	12,814,205	(123,958)	12,690,246
Segment profit	983,070	641,877	1,624,948	-	1,624,948
				Finance income	129,960
				Finance costs	(647,898)
				Profit before tax	1,107,010

Notes: 1. The intra-segment revenue and transfers are based on arm's length pricing.

2. Adjustments of revenue are in intra-segment revenue and transfers.

3. The segment profit reflects the operating profit in the summary of consolidated statements of income with adjustments.

Thousand yen

	Reportable segment			Adjustments	Consolidated
	Pharmaceutical	Medical Device	Total		
Depreciation and amortization	286,631	96,402	383,033	-	383,033

FY2022 (Jan 1, 2022 to Dec 31, 2022)

Thousand yen

	Reportable segment			Adjustments	Consolidated
	Pharmaceutical	Medical Device	Total		
Revenue					
(1) Revenue to outside customers	14,991,354	2,427,611	17,418,966	-	17,418,966
(2) Intra-segment revenue and transfers	-	93,750	93,750	(93,750)	-
Total	14,991,354	2,521,361	17,512,716	(93,750)	17,418,966
Segment profit	431,488	946,450	1,377,939	-	1,377,939
				Finance income	259,835
				Finance costs	(869,887)
				Profit before tax	767,887

- Note: 1. The intra-segment revenue and transfers are based on arm's length pricing.
 2. Adjustments of revenue are in intra-segment revenue and transfers.
 3. The segment profit reflects the operating profit in the summary of consolidated statements of income with adjustments.

Thousand yen

	Reportable segment			Adjustments	Consolidated
	Pharmaceutical	Medical Device	Total		
Depreciation and amortization	440,659	32,317	472,976	-	472,976

(3) Information related to products and services

Sales of products and services to outside customers are as follows.

Thousand yen

	FY2021 (Jan 1, 2021 to Dec 31, 2021)	FY2022 (Jan 1, 2022 to Dec 31, 2022)
ETUARY®	9,690,910	12,899,017
Biomaterial (bone grafts substitutes)	1,919,122	2,521,361
Other	1,080,213	1,998,586
Total	12,690,246	17,418,966

(4) Geographic information
 FY2021 (Jan 1, 2021 to Dec 31, 2021)

Thousand yen

	Japan	China	U.S.	Consolidated
Sales to outside customers (see note 1)	126,031	10,768,887	1,795,328	12,690,246
Non-current assets (see note 2)	77,257	3,953,297	6,946,968	10,977,523

Notes: 1. Measured based on customer location.
 2. Other financial assets and Deferred income tax assets are not included.

FY2022 (Jan 1, 2022 to Dec 31, 2022)

Thousand yen

	Japan	China	U.S.	Consolidated
Sales to outside customers (see note 1)	20,957	14,870,594	2,527,413	17,418,966
Non-current assets (see note 2)	344,754	5,193,027	8,145,124	13,682,906

Notes: 1. Measured based on customer location.
 2. Other financial assets, Deferred income tax assets and Investments accounted for using the equity method are not included.

(5) Information related to major customers
 FY2021 (Jan 1, 2021 to Dec 31, 2021)

Thousand yen

Customer name	Sales	Related segment
Sinopharm Holding Henan Co., Ltd	1,315,926	Pharmaceutical
Sinopharm holding Shandong Co., Ltd	632,136	Pharmaceutical
Sinopharm Holding Limited	478,334	Pharmaceutical
Beijing Keyuan Xinhai Pharmaceutical Management Co., Ltd	449,614	Pharmaceutical
K2M, Inc.	412,397	Medical Device

FY2022 (Jan 1, 2022 to Dec 31, 2022)

Thousand yen

Customer name	Sales	Related segment
Sinopharm	4,596,597	Pharmaceutical
China Resources Pharmaceutical	880,834	Pharmaceutical
Stryker Spine	633,006	Medical Device
Shanghai Pharma Kyuan	431,463	Pharmaceutical
OsteoRemedies	396,691	Medical Device

Notes: From FY2022, the customers are shown on a group company basis. Stryker Spine includes K2M, Inc. and Wright Medical. Sinopharm includes such firms as Sinopharm Holdings Limited, Sinopharm Holding Henan Co., Ltd, Sinopharm holdings Shandong Co., Ltd, and Sinopharm Holdings Shanxi Co., Ltd.

(Earnings per share)

Basic earnings per share and Diluted earnings per share and the basis for its calculation are as follows.

(1) Basic earnings per share

	FY2021 (Jan 1, 2021 to Dec 31, 2021)	FY2022 (Jan 1, 2022 to Dec 31, 2022)
Profit attributable to owners of the parent (thousand yen)	1,066,185	456,148
Average number of ordinary shares outstanding during the fiscal year (shares)	46,924,021	47,473,964
Basic earnings per share (yen)	22.72	9.61

(2) Diluted earnings per share

	FY2021 (Jan 1, 2021 to Dec 31, 2021)	FY2022 (Jan 1, 2022 to Dec 31, 2022)
Profit attributable to owners of the parent (thousand yen)	1,066,185	456,148
Average number of ordinary shares outstanding during the fiscal year (shares)	46,924,021	47,473,964
Adjustment of dilution effect:		
Stock option (shares)	1,366,372	457,152
Diluted average number of ordinary shares outstanding (shares)	48,290,393	47,931,116
Diluted earnings per share (yen)	22.08	9.52

(Important subsequent events)

Not applicable.