UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of report (Date of earliest event reported): **February 14, 2025**

Gyre Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**000-51173**	**56-2020050**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

12770 High Bluff Drive **Suite 150** **San Diego, CA**	**92130**
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: **(619) 949-3681**

N/A
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (*see* General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock	GYRE	The Nasdaq Capital Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02. Results of Operations and Financial Condition.

The information set forth below under "Preliminary Financial Information for the Year Ended December 31, 2024" in Item 7.01 is incorporated by reference herein.

Item 7.01. Regulation FD Disclosure.

Preliminary Financial Information for the Year Ended December 31, 2024

On February 14, 2025, GNI Group Ltd., a company incorporated under the laws of Japan with limited liability ("**GNI Group**"), which holds an indirect controlling interest of Gyre Therapeutics, Inc., a Delaware corporation (the "**Company**"), issued a press release reporting financial results for the quarter and year ended December 31, 2024. GNI Group also disclosed information regarding GNI Group's and the Company's financial position and near-term catalysts, including Gyre Pharmaceuticals Co., Ltd.'s ("**Gyre Pharmaceuticals**") expected topline data results for its Phase 3 clinical trial of Hydronidone in China in the first quarter of 2025 for patients with liver fibrosis caused by chronic hepatitis B, Gyre Pharmaceuticals' expected completion of its Phase 2 clinical trial of F573 for patients with acute liver failure and acute on chronic liver failure, Gyre Pharmaceuticals' expected initiation of its Phase 1 clinical trial of F230 for patients with pulmonary arterial hypertension and Gyre Pharmaceuticals' plan to submit a new investigational new drug application for F528 in December 2025.

A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated by reference herein. The exhibit furnished under Item 7.01 of this Current Report on Form 8-K shall not be deemed to be "filed" for purposes of Section 18 of the Exchange Act, or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Exchange Act or the Securities Act, regardless of any general incorporation language in such filing.

Forward Looking Statements

This report and the press release attached as an exhibit contain forward-looking statements that pertain to future operating performance and that are not historic facts. 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 and/or the Company, 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.

Item 9.01. Financial Statements and Exhibits.

(d) *Exhibits*. The following exhibits are being furnished herewith:

Exhibit Number	Exhibit Title or Description
99.1	Press Release, dated February 14, 2025
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

GYRE THERAPEUTICS, INC.

Date: **February 18, 2025**

By: /s/ Han Ying, Ph.D.
Name: Han Ying, Ph.D.
Title: Chief Executive Officer

Exhibit 99.1

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 FY2024 (IFRS)

February 14, 2025

Company Name: GNI Group Ltd. Tokyo Stock Exchange
Stock Code: 2160 URL https://www.gnipharma.com
Representative: Ying Luo, Director, Representative Executive Officer, President, and CEO
Inquiries: Toshiya Kitagawa, Director, Executive Officer, and CFO TEL: +81-3-6214-3600
Annual General Shareholder Meeting Date March 27, 2025
Annual financial report (Yuho) disclosure date: March 31, 2025
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 FY2024 (January to December)

(1) Consolidated Operating Results

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

	Revenue		Operating profit		Pre tax profit		Profit		Profit attributable to owners of parent		comprehensive income	
	Million yen	%	Million yen	%	Million yen	%	Million yen	%	Million yen	%	Million yen	%
FY2024	23,611	(9.2)	1,402	(89.3)	238	(98.1)	(130)	-	977	(87.9)	2,268	(78.7)
FY2023	26,010	49.3	13,108	851.3	12,612	-	9,504	-	8,094	-	10,662	-

	Basic earnings per share	Diluted earnings per share	Ratio of profit for the year to equity attributable to owners of parent	Ratio of pre tax profit to total assets	Ratio of operating profit to revenue
	Yen	Yen	%	%	%
FY2024	19.55	18.83	2.8	0.4	5.9
FY2023	169.50	165.56	29.6	26.2	50.4

(2) Consolidated Financial Position

	Total assets	Total equity	Total equity attributable to owners of parent	Ratio of total equity attributable to owners of parent	Total equity attributable to owners of parent per share
	Million yen	Million yen	Million yen	%	Yen
FY2024	69,947	39,673	36,405	52.0	725.87
FY2023	64,269	36,504	33,794	52.6	678.01

Notes: Provisional accounting treatments for business combinations are being finalized for the fiscal year ending December 2024, and the figures for the fiscal year ending December 2023 reflect the finalization of the provisional accounting treatments.

(3) Consolidated Cash Flows

	Cash flows from operating activities	Cash flows from investing activities	Cash flows from financing activities	Cash and cash equivalents at end of period
	Million yen	Million yen	Million yen	Million yen
FY2024	(3,164)	(10,361)	694	10,115
FY2023	6,549	(6,842)	10,686	21,633

2. Dividends

	Dividends per share					Total amount of dividends	Dividend payout ratio (consolidated)	Ratio of dividend to total equity attributable to owners of parent (consolidated)
	Q1	Q2	Q3	Year-End	Total			
	Yen	Yen	Yen	Yen	Yen	Million yen	%	%
FY2023	-	-	-	0.00	0.00	-	-	-
FY2024	-	-	-	0.00	0.00	-	-	-
FY2025 (Forecast)	-	-	-	0.00	0.00		-	

3. Consolidated Earnings Forecasts for FY2025 (January to December)

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

	Revenue		Operating profit		Pre-tax profit		Profit for the year		Profit attributable to owners of parent		Basic earnings per share
FY2025	Million yen	%	Million yen	%	Million yen	%	Million yen	%	Million yen	%	Yen
	28,733	21.7	23,217	-	22,541	-	15,868	-	12,058	-	240.42

For details regarding the performance forecasts above, please refer to the attached document "1. Analysis of Operating Results and Financial Position (5) Outlook for the Fiscal Year Ending December 31,2025"

Notes:

(1) Significant changes in the scope of consolidation during the period: Yes
Newly included: Governance Partners Asia Limited Partnership
Cullgen Australia Pty Ltd.
Excluded: -

(2) Changes in Accounting Policies and Changes in Accounting Estimates
① Changes in accounting policies that are required under IFRS: No
② Changes in accounting policies other than ① : No.
③ Changes in accounting estimates: No

(3) Number of Shares Issued (Ordinary Shares)

① Number of shares issued as of the end of the period (including treasury shares)	FY2024	50,168,243 shares	FY2023	49,857,243 shares
② Number of treasury shares as of the end of the period	FY2024	13,550 shares	FY2023	13,526 shares
③ Average number of shares for the period	FY2024	50,007,923 shares	FY2023	47,752,120 shares

* This consolidated financial report is not subject to review 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, 2025". The Group is planning to conduct a corporate presentation meeting for institutional investors and analysts on February 20, 2025. The presentation material for the meeting will be disclosed in advance, and the contents of the Q&A session, among other details, will be promptly disclosed after the meeting.

* Please note that "-" is used if YoY change ratio for the current period and the previous period is negative, or if the change ratio is above 1,000%.

Contents

1. Analysis of Operating Results and Financial Position

(1) Analysis of Operating Results

In 2024, the global economy remained uncertain due to high geopolitical risks such as the prolonged Russian invasion of Ukraine and instability in the Middle East. In Japan, the Nikkei average stock price has recorded its first 40,000 yen level, and a certain level of growth is being seen against the backdrop of a solid employment environment and a recovery in tourism demand. However, currency volatility has increased, and price inflation has been driven by rising import costs. On the other hand, the pace of wage increases continues to be unable to keep up with rising prices, and reducing the burden on households and addressing sustainable economic growth have become issues. As for the biotechnology sector to which our company belongs and the Tokyo Stock Exchange Growth Market, the situation is not entirely optimistic due to concerns over continued interest rate hikes in Japan.

Under these circumstances, GNI Group Co., Ltd. ("the Company" or "we") and its affiliated companies ("the Group") have been steadily promoting projects such as research and development, which the Group has been working on as a stepping stone to future business development, and the listing of subsidiary Cullgen Inc. ("Cullgen"), which have been undertaken by the Group as a whole, in order to become a global mid-sized pharmaceutical company.

In the pharmaceutical and drug discovery Segments, Beijing Continent Pharmaceuticals Co., Ltd. (doing business as Gyre Pharmaceuticals Co., Ltd. "Gyre Pharmaceuticals"), a major subsidiary of the Group, maintained total annual sales of its main product, ETUARY®, at the same level as last year, despite the anti-corruption campaign in the PRC lasting longer than expected. In order to gain a strong position in the pulmonary fibrosis field, we acquired the rights to manufacture and sell Nintedanib, which is indicated for pulmonary fibrosis other than Idiopathic Pulmonary Fibrosis (IPF) in May 2024. Furthermore, in the rare disease field (orphan drugs), Gyre Pharmaceuticals received manufacturing and commercial approval in June 2024 for avatrombopag maleate tablets, a treatment for thrombocytopenia due to chronic liver disease that it had been developing in the PRC and in January 2025, approval was granted for an expanded indication to include ITP (chronic idiopathic thrombocytopenia). As a result, it is expected that future sales revenue will increase by utilizing the existing sales network.

In October 2024, Gyre Pharmaceuticals completed the Phase 3 clinical trial in the PRC for F351, a promising candidate for the next product, targeting liver fibrosis caused by hepatitis B, and is working diligently to disclose top-line data from the clinical trial. In addition, Gyre Pharmaceuticals is exploring its future global expansion as a treatment for liver fibrosis caused by MASH (metabolic dysfunction-associated steatohepatitis).

As disclosed on November 14, 2024, Cullgen, a U.S. subsidiary that conducts research and development of innovative new drugs mainly in the U.S. and the PRC, announced that it will become a listed company on the Nasdaq market in the U.S. through a reverse merger. If successfully listed, it will be the second public company after Gyre Therapeutics.

Cullgen continues to advance drug discovery using its proprietary uSMITE™ (ubiquitin-mediated, small molecule induced target elimination) targeted protein degradation inducer technology platform. Cullgen has signed a joint research and option agreement with Astellas Pharma Inc. ("Astellas Pharma") to create innovative protein degradation inducers, and the joint research with Astellas Pharma in this strategic alliance is progressing smoothly.

Cullgen is currently conducting clinical trials in the PRC for CG001419 (development number) as the Company's first TRK degrader anticancer drug candidate, and has begun Phase 1/2 clinical trials. In addition, Cullgen established a subsidiary in Australia, its third country after the PRC and the U.S., and began the Phase 1 clinical trial for acute and chronic pain in January 2025. Moreover, as disclosed on October 9, 2024, the IND (Investigational New Drug Application) for CG009301 (development number), a treatment for malignant hematological tumors (leukemia) being developed in the PRC and the U.S. has been approved. Research and development are also underway for several other programs with the aim of starting clinical trials.

① Operating Results by Segment

Pharmaceutical Segment

The revenue of the main product of Gyre Pharmaceuticals, ETUARY® , remained steady in the Chinese market. Cullgen recorded revenue of JPY1,438 million from the joint development of targeted protein degraders with Astellas Pharma. As a result, the current consolidated fiscal year in the pharmaceutical segment, revenue and segment profit were JPY 18.3 billion down 20.3% YoY, and JPY0.3 billion, down 96.9% YoY, respectively. However, the segment profit remained steady, excluding a one-time revenue of upfront license fee from Astellas Pharma, and valuation gain on Gyre Therapeutics shares, both incurred in FY2023.

Medical Device Segment

In the Medical Device Segment, due to the inclusion of the newly established subsidiary in the consolidation last year, the segment revenue was JPY 5,307 billion, up 73.5% YoY, and the segment profit was JPY 10 billion, down 4.7% YoY, respectively.

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

Thousand yen

	FY2023	FY2024	Difference
Selling, general and administrative expenses	(15,292,839)	(15,771,868)	(479,029)
Personnel expenses	(5,318,748)	(5,074,682)	244,065
Research and development expenses	(2,557,803)	(2,811,801)	(253,998)

Selling, general and administrative (SG&A) expenses for FY2024 were JPY 15.7 billion, up 3.1% YoY.

Research and development (R&D) expenses for FY2024 were JPY 2.8 billion, up 9.9% YoY. The increase in R&D expenses was mainly due to the progress of preclinical and clinical trials at Cullgen.

③ Finance Income and Finance Costs

Thousand yen

	FY2023	FY2024	Difference
Finance income	771,527	707,799	(63,728)
Finance costs	(1,250,685)	(1,880,621)	(629,935)

Finance income

Finance income for FY2024 was JPY 707 million, down 8.3% YoY. This decrease of Finance Income was mainly due to decreased foreign exchange gain.

Finance costs

Finance costs for 2024 was JPY 1,880 million, up 50.4% YoY. This increase was mainly due to increased foreign exchange losses and non-cash interest expense related to Cullgen financing.

2) Analysis of Financial Position

The provisional accounting treatment for the business combination carried out in the previous consolidated fiscal year was finalized in this consolidated fiscal year. In accordance with the finalization of this provisional accounting treatment, the comparative information included in the consolidated financial statements for this consolidated fiscal year reflects a review of the initial allocation of the acquisition cost, and for comparison and analysis with the end of the previous consolidated fiscal year, the amount based on the final amount after reflecting this review is used.

Summary of Consolidated Financial Position

Thousand yen

	As of December 31, 2023	As of December 31, 2024	Difference
Total assets	64,269,302	69,947,020	5,677,718
Total liabilities	27,764,834	30,273,460	2,508,625
Total equity	36,504,467	39,673,560	3,169,092

Total assets
As of FY 2024 year-end, total assets stood at 69.9 billion, up 8.8% compared to the previous fiscal year end. This increase in total assets was mainly due to an increase in Non-current Intangible Assets.

Total liabilities
As of FY 2024 year-end, total liabilities stood at 30.2 billion, up 9.0% compared to the previous fiscal year end. This increase in total liabilities was mainly due to an increase in short-term borrowings.

Total equity
As of FY 2024 year-end, total equity stood at 39.6 billion, up 8.7% compared to the previous fiscal year end. This increase decrease was mainly due to increased other components of equity.

(3) Analysis of Cash Flows

Summary of Consolidated Cash Flows

Thousand yen

	FY2023	FY2024	Difference
Cash flows from operating activities	6,549,337	(3,164,422)	(9,713,759)
Cash flows from investing activities	(6,842,661)	(10,361,330)	(3,518,669)
Cash flows from financing activities	10,686,556	694,161	(9,992,394)

Cash flows from operating activities
The cash flow from operating activities was 3.1 billion (cash outflow) in FY2024 (it was 6.5 billion cash inflow in FY2023). This outflow of cash was mainly due to increased payment of corporate income taxes.

Cash flows from investing activities
The cash flow from investing activities was 10.3 billion (cash outflow) in FY2024 (it was 6.8 billion cash outflow in FY2023). This was mainly due to an increase in leasehold and guarantee deposits and the purchase of securities.

Cash flows from financing activities
The cash flow from financing activities was 0.6 billion (cash inflow) in FY2024 (it was 10.6 billion cash inflow in FY2023). This was mainly due to an increase in short-term borrowings, and inflow from capital contribution from non-controlling interests.

(4) Research and Dvelopment Ativities

[Research Activities]
The Group's drug discovery research aims to develop innovative new candidate compounds (NCEs) centered around Cullgen. Cullgen is conducting research and development to expand its drug discovery pipeline, which includes multiple novel compounds targeting enzyme and non-enzyme proteins for cancer, pain, and autoimmune diseases.

In June 2023, Cullgen entered into a collaboration and exclusive option agreement with Astellas Pharma to create innovative protein degradation inducers. In this strategic alliance, the two companies will combine Cullgen's proprietary technology platform uSMITE™ utilizing novel E3 ligands with Astellas Pharma's drug discovery and commercialization capabilities to create multiple targeted protein degradation inducers. Cullgen and Astellas Pharma will collaborate to discover compounds for clinical development, and Astellas Pharma will be responsible for the development and commercialization of the discovered degraders. Collaborative research with Astellas Pharma, including candidate degraders for cell cycle proteins, which are lead programs identified by Astellas Pharma for breast cancer and other solid cancers, is progressing smoothly.

[Development Activities]
■ ETUARY® [Chinese: 艾思瑞® , (Generic name: Pirfenidone)] - Gyre Pharmaceuticals
Gyre Pharmaceuticals is conducting clinical trials to expand the indications of ETUARY® to the following diseases:
- •Diabetic nephropathy (DKD): Phase 1 clinical trials completed, discussing further steps with Chinese authorities
- •Connective Tissue Diseases Associated Interstitial Lung Disease (CTD-LID) (systemic sclerosis (SSc-ILD) and dermatomyositis (DM-ILD)): Phase 3 clinical trials ongoing
- • Pneumoconiosis treatment drug (Pneumoconiosis, PD): Phase 3 clinical trials ongoing

■ Nintedanib - Gyre Pharmaceuticals
Nintedanib is a treatment drug indicated for IPF, systemic sclerosis-associated interstitial lung disease (SSc-ILD) and progressive fibrotic interstitial lung disease (PF-ILD). In May 2024, Gyre Pharmaceuticals acquired the rights to manufacturing and commercial rights from Jiangsu Vanguard Pharmaceutical Co., Ltd..

■ F351 (Generic name: Hydronidone) - Gyre Pharmaceuticals and Gyre Therapeutics
F351 is a potential treatment for liver fibrosis and an important new drug candidate in our pharmaceutical portfolio, which will be a key part of our strategy to enter major pharmaceutical markets around the world. F351 is a potential blockbuster drug candidate.

Gyre Pharmaceuticals completed the Phase 3 clinical trial in patients with liver fibrosis caused by chronic hepatitis B in the PRC in October 2024. The top-line results of Phase 3 are expected to be released in Q1 2025.

Gyre Pharmaceuticals is exploring its future global expansion as a treatment for liver fibrosis caused by MASH (metabolic dysfunction-associated steatohepatitis).

■ F573 [for Acute Liver Failure (ALF) and Acute on Chronic Liver Failure (ACLF)] - Gyre Pharmaceuticals
Gyre Pharmaceuticals is conducting the Phase 2 clinical trial of F573 as a treatment for ALF/ACLF, with the Phase 2 clinical trial is expected to be completed by the end of 2026.

■ F230 [for Pulmonary Arterial Hypertension (PAH)] - Gyre Pharmaceuticals
F230 is a drug in collaboration with Eisai for the treatment of PAH, and Gyre Pharmaceuticals received IND (Investigative Drug Application) approval in the PRC in May 2024. The Phase 1 clinical trial is scheduled to begin in May 2025.

■ F528 [for Chronic Obstructive Pulmonary Disease (COPD)] - Gyre Pharmaceuticals
F528 is a novel anti-inflammatory agent that suppresses multiple inflammatory cytokines, and Gyre Pharmaceuticals is conducting research and development of it as a new drug candidate that may reduce the progression of COPD. IND application is planned for December 2025.

■ CG001419 (TRK degrader) - Cullgen
CG001419 is an oral drug utilizing the industry's first selective and potent targeted protein degrader. In July 2023, Cullgen initiated its first clinical trial (Phase 1/2) for the TRK degrader in the PRC. In addition, in January 2025, Cullgen began the Phase 1 clinical trial in Australia for acute and chronic pain.

■ CG009301 (malignant hematologic tumor (leukemia) treatment) – Cullgen
CG009301 is a novel degrader targeting the GSPT1 protein, and the National Medical Products Administration (NMPA) approved the IND in October 2024. We will move to clinical trials promptly.

■ Other Generic Orphan Drugs - Gyre Pharmaceuticals
Gyre Pharmaceuticals obtained sales approval for avatrombopag maleate tablets, a treatment for thrombocytopenia due to chronic liver disease, to expand its pipeline of orphan drugs in June 2024, and received approval to expand the indication to include ITP (chronic idiopathic thrombocytopenia) in January 2025.

(5) Outlook for the Fiscal Year Ending December 31, 2025

In the fiscal year 2025, we expect the sales revenue and profits of our core business, the Pharmaceutical Segment, to remain strong. Gyre Pharmaceuticals is expected to continue to lead our group by leveraging its existing sales network and expanding its sales lineup. In addition, we anticipate Cullgen to make steady progress in research and development. Further, we announced that we expect to record other income of approximately 14,764 million yen (including approximately 10,768 million yen in stock valuation gains) in connection with our listing on the Nasdaq market through a reverse merger with Pulmatrix, Inc.. The timing of converting Cullgen's preferred shares into common shares and valuing them at market value will be determined by the opening price on the day of Cullgen's public offering. Cullgen's milestone revenue are not included in our earnings forecast for the fiscal year 2025.

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

	FY2023 (As of Dec 31, 2023)	FY2024 (As of Dec 31, 2024)
Assets		
Non-current assets		
Property, plant and equipment	5,079,299	5,696,491
Right-of-use assets	814,513	1,559,345
Goodwill	14,246,433	15,994,981
Intangible assets	8,852,943	11,026,585
Investments accounted for using the equity method	360,821	386,978
Deferred tax assets	304,436	238,914
Other financial assets	3,793,224	5,764,350
Other non-current assets	23,811	56,730
Total non-current assets	33,475,483	40,724,377
Current assets		
Inventories	2,217,158	2,529,642
Trade and other receivables	3,973,476	6,236,284
Other financial assets	1,577,274	9,291,037
Other current assets	1,392,881	1,050,642
Cash and cash equivalents	21,633,028	10,115,037
Total current assets	30,793,818	29,222,643
Total assets	64,269,302	69,947,020
Liabilities and equity		
Non-current liabilities		
Loans Payable	1,600,000	1,200,000
Lease liabilities	150,276	735,590
Deferred tax liabilities	2,363,680	1,785,240
Other financial liabilities	15,139,232	15,454,160
Other non-current liabilities	85,146	203,422
Total non-current liabilities	19,338,336	19,378,414
Current liabilities		
Trade and other payables	2,064,776	2,263,911
Borrowings	1,300,000	4,575,000
Current portion of long-term borrowings	400,000	400,000
Lease liabilities	249,158	295,289
Current tax payable	2,187,700	1,041,718
Other financial liabilities	49,010	888
Other current liabilities	2,175,853	2,318,237
Total current liabilities	8,426,498	10,895,045
Total liabilities	27,764,834	30,273,460

(1) Consolidated Statements of Financial Position

Thousand yen

	FY2023 (As of Dec 31, 2023)	FY2024 (As of Dec 31, 2024)
Equity		
Share capital	13,052,056	13,276,700
Capital surplus	7,397,974	6,626,254
Treasury shares	(15,302)	(15,372)
Retained earnings (loss)	8,790,563	9,768,222
Other components of equity	4,569,122	6,749,971
Total equity attributable to owners of parent	33,794,414	36,405,775
Non-controlling interests	2,710,053	3,267,785
Total equity	36,504,467	39,673,560
Total equity and liabilities	64,269,302	69,947,020

(2) Consolidated Statements of Income and Consolidated Statements of Comprehensive Income

Consolidated Statements of Income

Thousand yen

	FY2023 (Jan 1, 2023 to Dec 31, 2023)	FY2024 (Jan 1, 2024 to Dec 31, 2024)
Revenue	26,010,571	23,611,705
Cost of sales	(3,579,396)	(5,574,590)
Gross profit	22,431,175	18,037,115
Selling, general and administrative expenses	(15,292,839)	(15,771,868)
Research and development expenses	(2,557,803)	(2,811,801)
Other income	9,147,345	2,434,432
Other expenses	(619,035)	(485,576)
Operating profit	13,108,843	1,402,301
Finance income	771,527	707,799
Finance costs	(1,250,685)	(1,880,621)
Equity Losses of Affiliated Companies	(16,936)	8,705
Profit before tax	12,612,748	238,185
Income tax expense	(3,108,669)	(368,324)
Profit (loss) for the year	9,504,078	(130,139)
Profit (loss) attributable to:		
Owners of parent	8,094,202	977,658
Non-controlling interests	1,409,875	(1,107,798)
Earnings per share		
Basic earnings per share (Yen)	169.50	19.55
Diluted earnings per share (Yen)	165.56	18.83

Consolidated Statements of Comprehensive Income

Thousand yen

	FY2023 (Jan 1, 2023 to Dec 31, 2023)	FY2024 (Jan 1, 2024 to Dec 31, 2024)
Profit (loss) for the year	9,504,078	(130,139)
Other comprehensive income		
Items that may be reclassified to profit or loss, net of tax		
Exchange differences on translation of foreign operations	1,150,717	2,367,183
Share in Other Comprehensive Income for Equity Method Investees	7,824	31,895
Total other comprehensive income	1,158,541	2,399,079
Total comprehensive income for the year	10,662,620	2,268,939
Total comprehensive income for the year attributable to:		
Owners of the parent	8,916,299	3,100,605
Non-controlling interests	1,746,321	(831,665)

(3) Consolidated Statements of Changes in Equity

Thousand yen

	Attributable to owners of parent						
					Other components of equity		
	Share capital	Capital surplus	Treasury shares	Retained earnings	Subscription rights to shares	Exch. diff on translation of foreign operations	Total
Balance as of Jan 1, 2023	10,893,070	6,233,386	(756)	696,360	824,192	2,323,439	3,147,631
Profit for the year	-	-	-	8,094,202	-	-	-
Other comprehensive income	-	-	-	-	-	822,096	822,096
Total comprehensive income	-	-	-	8,094,202	-	822,096	822,096
Change in scope of consolidation	-	-	-	-	-	-	-
Changes in ownership interest in subsidiaries	-	(999,553)	-	-	-	(80,129)	(80,129)
Issuance of new shares	2,166,261	2,166,261	-	-	-	-	-
Share issue costs	(7,275)	(7,275)	-	-	-	-	-
Share-based payment transactions	-	-	-	-	755,072	-	755,072
Issuance of share acquisition rights	-	-	-	-	5,568	-	5,568
SRS issuance cost	-	-	-	-	(7,124)	-	(7,124)
Exercise of share acquisition rights	-	-	-	-	(16,394)	-	(16,394)
Cancellation of share acquisition rights					(35,872)		(35,872)
Forfeiture of share acquisition rights	-	-	-	-	(21,725)	-	(21,725)
Purchase of treasury shares	-	-	(14,546)	-	-	-	-
Other	-	5,155	-	-	-	-	-
Total amount of transactions with owners	2,158,985	1,164,587	(14,546)	-	679,524	(80,129)	599,394
Balance as of Dec 31, 2023	13,052,056	7,397,974	(15,302)	8,790,563	1,503,717	3,065,405	4,569,122

	Equity attributable to owners of parent	Non-controlling interests	Total equity
	Total		
Balance as of Jan 1 2023	20,969,692	(1,158,724)	19,810,968
Profit for the year	8,094,202	1,409,875	9,504,078
Other comprehensive income	822,096	336,445	1,158,541
Total comprehensive income	8,916,299	1,746,321	10,662,620
Change in scope of consolidation	-	1,042,772	1,042,772
Changes in ownership interest in subsidiaries	(1,079,683)	1,079,683	-
Issuance of new shares	4,332,523	-	4,332,523
Share issue costs	(14,551)	-	(14,551)
Share-based payment transactions	755,072	-	755,072
Issuance of share acquisition rights	5,568	-	5,568
SRS issuance cost	(7,124)	-	(7,124)
Exercise of share acquisition rights	(16,394)	-	(16,394)
Cancellation of share acquisition rights	(35,872)		(35,872)
Forfeiture of share acquisition rights	(21,725)	-	(21,725)
Purchase of treasury shares	(14,546)	-	(14,546)
Other	5,155	-	5,155
Total amount of transactions with owners	3,908,421	2,122,456	6,030,878
Balance as of Dec 31 2023	33,794,414	2,710,053	36,504,467

Thousand yen

	Attributable to owners of parent						
					Other components of equity		
	Share capital	Capital surplus	Treasury shares	Retained earnings	Subscription rights to shares	Exch. diff on translation of foreign operations	Total
Balance as of Jan 1, 2024	13,052,056	7,397,974	(15,302)	8,790,563	1,503,717	3,065,405	4,569,122
Profit (loss) for the year	-	-	-	977,658	-	-	-
Other comprehensive income	-	-	-	-	-	2,122,946	2,122,946
Total comprehensive income	-	-	-	977,658	-	2,122,946	2,122,946
Change in scope of consolidation	-	-	-	-	-	-	-
Changes in ownership interest in subsidiaries	-	(996,363)	-	-	-	(55,221)	(55,221)
Issuance of new shares	227,911	227,911	-	-	-	-	-
Stock issue costs	(3,267)	(3,267)	-	-	-	-	-
Share-based payment transactions	-	-	-	-	239,437	-	239,437
Issuance of share acquisition rights	-	-	-	-	326	-	326
Issuance cost of share acquisition rights	-	-	-	-	(4,958)	-	(4,958)
Exercise of share acquisition rights	-	-	-	-	(121,682)	-	(121,682)
Purchase of treasury shares	-	-	(69)	-	-	-	-
Total amount of transactions with owners	224,644	(771,719)	(69)	-	113,122	(55,221)	57,901
Balance as of Dec 31, 2024	13,276,700	6,626,254	(15,372)	9,768,222	1,616,839	5,133,131	6,749,971

	Equity attributable to owners of parent	Non-controlling interests	Total equity
	Total		
Balance as of Jan 1 2024	33,794,414	2,710,053	36,504,467
Profit (loss) for the year	977,658	(1,107,798)	(130,139)
Other comprehensive income	2,122,946	276,132	2,399,079
Total comprehensive income	3,100,605	(831,665)	2,268,939
Change in scope of consolidation	-	91,244	91,244
Changes in ownership interest in subsidiaries	(1,051,584)	1,298,152	246,567
Issuance of new shares	455,822	-	455,822
Stock issue costs	(6,534)	-	(6,534)
Share-based payment transactions	239,437	-	239,437
Issuance of share acquisition rights	326	-	326
Issuance cost of share acquisition right	(4,958)	-	(4,958)
Exercise of share acquisition rights	(121,682)	-	(121,682)
Purchase of treasury shares	(69)	-	(69)
Total amount of transactions with owners	(489,244)	1,389,397	900,152
Balance as of Dec 31 2024	36,405,775	3,267,785	39,673,560

(4) Consolidated Statements of Cash Flows

Thousand yen

	FY2023 (Jan 1, 2023 to Dec 31, 2023)	FY2024 (Jan 1, 2024 to Dec 31, 2024)
Cash flows from operating activities		
Profit before tax	12,612,748	238,185
Depreciation	608,422	983,243
Decrease (increase) in trade and other receivables	324,379	(1,865,768)
Increase (decrease) in trade and other payables	6,280	(3,607)
Decrease (increase) in inventories	145,761	(90,023)
Bonus allowance	16,212	17,526
Finance income and finance costs	877,467	752,336
Loss (gain) on Valuation in securities	291,808	(41,910)
Gain on valuation of conversion of shares of associates to subsidiaries	(8,969,727)	-
Share-based payment expenses	1,161,004	239,767
Other	591,026	(1,600,319)
Subtotal	7,665,385	(1,370,570)
Interest received	494,185	503,919
Interest paid	(30,795)	(103,733)
Income taxes paid	(1,579,438)	(2,194,037)
Net cash provided by (used in) operating activities	6,549,337	(3,164,422)
Cash flows from investing activities		
Net decrease (increase) in time deposits	(3,491,108)	(1,199,063)
Purchase of securities	-	(4,066,617)
Purchases of property, plant and equipment	(1,273,154)	(522,835)
Proceeds from sales of property, plant and equipment	15,208	1,620
Purchase of intangible assets	(802,823)	(1,013,834)
Increase of leasehold and guarantee deposits	(3,831)	(2,066,754)
Decrease of leasehold and guarantee deposits	1,203	18,538
Payments for loans receivable	(59,460)	-
Collection of loans receivable	4,743	-
Purchase of investment securities	-	(1,703,102)
Proceeds from sale of investment securities	-	190,718
Investment to affiliated companies	(140,670)	-
Proceeds from purchase of shares of subsidiaries resulting in change in scope of consolidation	954,505	-
Payments for acquisition of businesses	(2,047,274)	-
Net cash provided by (used in) investing activities	(6,842,661)	(10,361,330)
Cash flows from financing activities		
Net increase (decrease) in short-term borrowings	1,100,000	3,275,000
Proceeds from long-term borrowings	2,000,000	-
Repayments of long-term borrowings	-	(400,000)
Proceeds from exercise of share acquisition rights	4,287,054	727,324
Proceeds from issuance of share acquisition rights	798	326
Capital contribution from non-controlling interests	3,516,749	741,982
Payments for acquisition of interests in subsidiaries from non-controlling interests	-	(3,269,100)
Purchase of treasury shares	(38)	(69)
Repayment of lease liabilities	(218,008)	(381,303)
Net cash provided by (used in) financing activities	10,686,556	694,161

	FY2023 (Jan 1, 2023 to Dec 31, 2023)	FY2024 (Jan 1, 2024 to Dec 31, 2024)
Effect of exchange rate changes on cash and cash equivalents	190,485	1,313,601
Net increase (decrease) in cash and cash equivalents	10,583,717	(11,517,990)
Cash and cash equivalents at beginning of the period	11,049,310	21,633,028
Cash and cash equivalents at the end of the period	21,633,028	10,115,037

(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 312 of the same.

(2) Functional currency and presentation currency

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

(3) 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 of medical devices including biomaterials.

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; Shanghai Genomics Technology, Ltd.; Cullgen (Shanghai), Inc.; GNI USA, Inc.; Cullgen Inc.; Shanghai Rui Fu International Trade Co., Ltd.; Gyre Therapeutics, Inc.	ETUARY®, drug discovery and development, reagents etc.
Medical Device	Berkeley Advanced Biomaterials LLC, Micren Healthcare Co., Ltd., Berkeley Biologics LLC	Biomaterials, Designated Marketing Authorization Holder (DMAH) and in-country caretaker (ICC) service

(2) Reportable segment revenue and profit

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

FY2023 (Jan 1, 2023 to Dec 31, 2023)

Thousand yen

	Reportable segments			Adjustments	Consolidated
	Pharmaceutical	Medical Device	Total		
Revenue					
(1) Revenue to outside customers	22,976,201	3,034,369	26,010,571	-	26,010,571
(2) Intra-segment revenue and transfers	-	24,171	24,171	(24,171)	-
Total	22,976,201	3,058,541	26,034,742	(24,171)	26,010,571
Segment profit	12,026,795	1,082,048	13,108,843	-	13,108,843
				Finance income	771,527
				Finance costs	(1,250,685)
				Share of profit (loss) of investments accounted for using equity method	(16,936)
				Profit before tax	12,612,748

Notes:
1. Intra-segment revenue and transfers are based on arm's-length prices.
2. The adjustment of revenue reflects intra-segment revenue.
3. The segment profit reflects the operating profit in the summary of the consolidated statements of income .

Thousand yen

	Reportable segments			Adjustments	Consolidated
	Pharmaceutical	Medical Device	Total		
Depreciation	440,438	167,983	608,422	-	608,422

FY2024 (Jan 1, 2024 to Dec 31, 2024)

Thousand yen

	Reportable segments			Adjustments	Consolidated
	Pharmaceutical	Medical Device	Total		
Revenue					
(1) Revenue to outside customers	18,303,785	5,307,920	23,611,705	-	23,611,705
(2) Intra-segment revenue and transfers	-	-	-	-	-
Total	18,303,785	5,307,920	23,611,705	-	23,611,705
Segment profit	371,073	1,031,227	1,402,301	-	1,402,301
				Finance income	707,799
				Finance costs	(1,880,621)
				Share of profit (loss) of investments accounted for using equity method	8,705
				Profit before tax	238,185

Notes:
1. Intra-segment revenue and transfers are based on arm's-length prices.
2. The adjustment of revenue reflects intra-segment revenue.
3. The segment profit reflects the operating profit in the summary of the consolidated statements of income.

Thousand yen

	Reportable segments			Adjustments	Consolidated
	Pharmaceutical	Medical Device	Total		
Depreciation	637,094	346,148	983,243	-	983,243

(3) Information related to products and services

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

Thousand yen

	FY2023 (Jan 1, 2023 to Dec 31, 2023)	FY2024 (Jan 1, 2024 to Dec 31, 2024)
ETUARY®	15,686,480	15,738,090
Biomaterial	2,840,558	5,169,102
Other	7,483,532	2,704,513
Total	26,010,571	23,611,705

(4) Geographic information

FY2023 (Jan 1, 2023 to Dec 31, 2023)

Thousand yen

	Japan	China	U.S.	Consolidated
Sales to outside customers (see note 1)	6,021,269	17,123,029	2,866,272	26,010,571
Non-current assets (see note 2)	306,483	7,048,392	19,673,729	27,028,605

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

FY2024 (Jan 1, 2024 to Dec 31, 2024)

Thousand yen

	Japan	China	U.S.	Consolidated
Sales to outside customers (see note 1)	1,462,983	17,098,945	5,049,776	23,611,705
Non-current assets (see note 2)	423,932	9,432,683	24,477,517	34,334,134

Notes: 1. Sales amounts are 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

FY2023 (Jan 1, 2023 to Dec 31, 2023)

Thousand yen

Customer name	Sales	Related segment
Astellas Pharma Inc.	5,804,973	Pharmaceutical
Sinopharm	5,365,748	Pharmaceutical
China Resources Pharmaceutical	1,575,165	Pharmaceutical
Shanghai Pharma	711,361	Pharmaceutical
Lawson	643,195	Pharmaceutical

FY2024 (Jan 1, 2024 to Dec 31, 2024)

Thousand yen

Customer name	Sales	Related segment
Sinopharm	5,105,295	Pharmaceutical
China Resources Pharmaceutical	1,616,847	Pharmaceutical
Astellas Pharma Inc.	1,438,586	Pharmaceutical
Stryker Spine	819,845	Medical Device
Huadong Medicine Co., Ltd.	747,923	Pharmaceutical

(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

	FY2023 (Jan 1, 2023 to Dec 31, 2023)	FY2024 (Jan 1, 2024 to Dec 31, 2024)
Profit attributable to owners of parent (thousand yen)	8,094,202	977,658
Average number of ordinary shares outstanding during the fiscal year (shares)	47,752,120	50,007,923
Basic earnings per share (yen)	169.50	19.55

(2) Diluted earnings per share

	FY2023 (Jan 1, 2023, to Dec 31, 2023)	FY2024 (Jan 1, 2024, to Dec 31, 2024)
Profit attributable to owners of parent (thousand yen)	8,094,202	977,658
Average number of ordinary shares outstanding during the fiscal year (shares)	47,752,120	50,007,923
Adjustment of dilution effect:		
Stock option (shares)	1,138,640	1,914,392
Diluted average number of ordinary shares outstanding (shares)	48,890,760	51,922,315
Diluted earnings per share (yen)	165.56	18.83

(Important Subsequent Events)

No Important Subsequent Event