

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): **November 14, 2023**

Gyre Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of incorporation)

000-51173
(Commission File Number)

56-2020050
(IRS Employer Identification No.)

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

92130
(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 7.01. Regulation FD Disclosure.

On November 14, 2023, GNI Group Ltd., a company incorporated under the laws of Japan with limited liability (“GNI Japan”), which holds an indirect controlling interest of Gyre Therapeutics, Inc., a Delaware corporation (the “Company”), filed its third quarter report for the fiscal year ending December 2023 (the “Report of GNI Japan”).

A copy of the Report of GNI Japan 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 Report of GNI Japan 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 Japan 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	Report of GNI Japan, dated November 14, 2023
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: **November 14, 2023**

By: /s/ Charles C. Wu, Ph.D.

Name: Charles C. Wu, Ph.D.

Title: Chief Executive Officer

Quarterly Report

(3Q of 23rd Fiscal Period)

July 1, 2023
To September 30, 2023

GNI Group Ltd.

2-2, Nihonbashi-Honcho 2-chome, Chuo-ku, Tokyo

Contents

[Cover]	3
1st Section [Corporate Information]	4
1st [Overview of the Company]	4
1 [Trends in Major Management Indicators]	4
2 [Description of business]	4
Second [Business Conditions]	4
1 [Business Risks]	5
2 [Management's Discussion and Analysis of Financial Condition, Results of Operations and Cash Flows]	5
3 [Significant Management Contracts]	9
Third [Status of the Filing Company]	10
1 [Status of Shares]	10
(1)[Total Number of Shares]	10
①[Total number of shares]	10
②[Issued Shares]	10
(2)[Status of Stock Acquisition Rights]	11
①[Details of stock option plan]	11
②[Status of other stock acquisition rights]	15
(3)[Status of Exercise of Bonds with Stock Acquisition Rights with Exercise Price Adjustment, etc.]	16
(4)[Changes in the number of issued shares, capital stock, etc.]	16
(5)[Major Shareholders]	16
(6)[Status of voting rights]	16
①[Issued Shares]	16
②[Treasury stock]	16
2 [Status of officers]	17
Fourth [Status of Accounting]	18
1 [Condensed Quarterly Consolidated Financial Statements]	19
(1)[Condensed Quarterly Consolidated Statements of Financial Position]	19
(2)[Condensed Quarterly Consolidated Statements of Income and Condensed Quarterly Consolidated Statements of Comprehensive Income]	20
[Condensed Quarterly Consolidated Statements of Income]	20
[Cumulative 3Q]	20
[3Q Consolidated Fiscal Year]	21
[Condensed Quarterly Consolidated Statement of Comprehensive Income]	22
[Cumulative 3Q]	22
[3Q Consolidated Fiscal Year]	23
(3)[Condensed Quarterly Consolidated Statement of Changes in Equity]	24
(4)[Condensed Quarterly Consolidated Statements of Cash Flows]	26
[Notes to the Condensed Quarterly Consolidated Financial Statements]	27
2 [Others]	39
Part II [Information on Guarantee Companies, etc. of Submitting Companies]	40
[Quarterly Review Report]	41

[Cover]

[Filing]	Quarterly Report
[Articles of Basis]	Article 24-4-7(1) of the Financial Instruments and Exchange Act
[Submit to]	Kanto Finance Bureau
[Submission date]	November 14, 2023
[Quarterly accounting period]	3Q of 2023rd Fiscal Period (From July 1, 2023 to September 30, 2023)
[Company Name]	GNI Group Ltd.
[English translation name]	GNI Group Ltd.
[Title of Representative]	CEO Ying Luo, Director, Representative Executive Officer, President and CEO
[Location of the head office]	2-2, Nihonbashi-Honcho 2-chome, Chuo-ku, Tokyo
[Phone No.]	03(6214) 3600 (Representative)
[Name of administrative liaison]	Toshiya Kitagawa Executive Officer and CFO
[Near contact location]	2-2, Nihonbashi-Honcho 2-chome, Chuo-ku, Tokyo
[Phone No.]	03(6214) 3600 (Representative)
[Name of administrative liaison]	Toshiya Kitagawa Executive Officer and CFO
[Locations for Public Inspection]	Tokyo Stock Exchange, Inc. (2-1, Nihonbashi Kabutocho, Chuo-ku, Tokyo)

1 [Trends in Major Management Indicators]

Next time Accounting period		22nd	23rd	22nd
		3rd quarter Consolidated Cumulative Period January 1, 2022 To September 30, 2022	3rd quarter Consolidated Cumulative Period January 1, 2023 To September 30, 2023	January 1, 2022 To December 31, 2022
Revenue	(thousand yen)	12,761,031	20,547,895	17,418,966
(3Q Consolidated Accounting Period)		(4,606,213)	(6,451,350)	
Quarterly (current) income before income taxes	(thousand yen)	1,223,079	6,376,072	767,887
Quarterly (current) income	(thousand yen)	324,416	4,804,496	△868,252
Quarterly profit attributable to owners of the parent	(thousand yen)	1,076,065	2,213,274	388,825
(3Q Consolidated Accounting Period)		(399,618)	(554,468)	
Quarterly (current term) Total comprehensive income	(thousand yen)	2,535,079	6,661,304	187,696
Quarterly (current term) comprehensive income attributable to owners of the parent	(thousand yen)	3,833,451	3,907,869	1,811,272
Equity attributable to owners of the parent company	(thousand yen)	22,908,103	24,220,114	20,969,692
Total assets	(thousand yen)	36,456,893	48,468,006	33,906,981
Quarterly (current) income per share (basic)	(Yen)	22.67	46.61	8.19
(3Q Consolidated Accounting Period)		(8.42)	(11.68)	
Quarterly (current) incomes per diluted share	(Yen)	22.46	46.13	8.11
Ratio of equity attributable to owners of the parent to total assets	(%)	62.8	50.0	61.8
Net cash provided by operating activities	(thousand yen)	△162,928	4,442,988	393,320
Net cash used in investing activities	(thousand yen)	△2,909,505	△3,697,727	△4,116,163
Net cash used in financing activities	(thousand yen)	△299,280	4,981,492	△646,327
Cash and cash equivalents at end of quarter (year-end)	(thousand yen)	12,722,213	18,142,601	11,049,310

(NOTE) 1. We have prepared the condensed quarterly consolidated financial statements. Therefore, we have not presented any changes in the main management indicators, etc. of the submitting company.

2. The above indicators are based on the condensed quarterly consolidated and combined financial statements prepared in accordance with International Financial Reporting Standards (IFRS).

2 [Description of business]

Our group consists of the company submitting consolidated financial statements (hereafter, "we") and 15 consolidated subsidiaries and 3 affiliated companies. The business content of these companies is classified into the pharmaceutical business and the medical device business. In the pharmaceuticals business, the Group conducts R&D, manufacturing, and sales of ETUARY®, which is marketed in the Chinese market, and F351, which is under clinical trials. In the medical device business, the Group develops, manufactures and sells medical devices (biomaterials) based in the United States.

Changes in major affiliated companies related to each segment in the 3Q of the current fiscal year are generally as follows.

<Pharmaceutical> No changes in major affiliates.

<Medical Device> No changes in major affiliates.

Second [Business Conditions]

1 [Business Risks]

There have been no significant changes in the status of business, accounting and other matters described in this quarterly report during the 3Q of the fiscal year under review that could have a significant impact on investors' decisions or the "Business Risks" described in the previous fiscal year's securities report.

2 [Management's Discussion and Analysis of Financial Condition, Results of Operations and Cash Flows]

Forward-looking statements are based on judgments as of the end of the 3Q of the current fiscal year.

(1) Operating and financial review

During the first nine months of the current fiscal year, the Japanese economy showed a gradual recovery trend as socioeconomic activities normalized following the shift of new coronavirus infection to "category 5" infection. On the other hand, the global economy remained uncertain against the backdrop of prolonged geopolitical risks and rising prices and interest rates worldwide. Similarly, in the biotechnology sector, the global outlook has yet to be completely cleared.

Despite these circumstances, the GNI Group Inc. and its affiliated companies ("the Group") achieved year-on-year increases in revenue in its main businesses.

In particular, sales of ETUARY®, the main product of Beijing Continent Pharmaceutical Co., Ltd. ("BC"), a major subsidiary of our group, remained strong, contributing significantly to the revenue increase. BC is proceeding with Phase III clinical trials in China for F351, which is a strong candidate for its next product, and the trial is making steady progress with patient enrollment expected to be completed by the end of 2023.

With respect to the transaction with Catalyst Biosciences, Inc. ("CBIO"), a U.S. Nasdaq-listed company, disclosed in December 2022, the Group has completed Transaction 1 to transfer the non-Chinese rights of F351 to CBIO and is now planning to transfer the BC shares held by the Group to CBIO by way of an investment in kind. At the general meeting of CBIO shareholders held on August 29, 2023, all related agenda items were approved.

Cullgen Inc. ("Cullgen"), a US subsidiary specializing in research and development mainly in The United States and China, continues to make a steady progress utilizing a proprietary target protein degradation technology platform uSMITE™ (ubiquitin-mediated, small molecule induced target elimination). As disclosed in June 2023, Cullgen has entered into a collaboration and exclusive option agreement with Astellas Pharma Inc. ("Astellas") for the development of innovative protein degraders. The joint research with Astellas under this strategic alliance is progressing well. Cullgen is also advancing the clinical trial in China for its first TRK-degrader oncology drug candidate and, as disclosed in July 2023, has initiated Phase I/II clinical trials, its first clinical trial in humans. At the same time, we are developing several other programs targeting to submit IND's for clinical trials.

In the medical device business, the performance has been strong led by Berkeley Advanced Biomaterials LLC ("BAB"), which is engaged in the biomaterials business in the United States. In order to further enhance the biomaterials business, as disclosed on September 19, 2023, the Group has decided to acquired a portion of the orthobiologics business from Elutia Inc, (Nasdaq-listed; ticker: ELUT; "Elutia"), which develops and commercializes biologics in the United States, subject to the successful completion of due diligence, and to establish a wholly owned subsidiary in the United States that will serve as the entity to run that business, and the due diligence is underway. In addition, as disclosed on August 1, 2023, the Group has started consolidating per the equity method Shanghai JIUCE Medical Device Technology Co., Ltd, which is BAB's existing distributor and focuses on marketing imported medical devices and consumables, in order to expand the medical device business in China going forward.

④ Operating Results by Segment

Pharmaceutical Business

Revenue from ETUARY®, BC's flagship product, in the Chinese marketplace remained firm. In addition, we recorded revenue of JPY4.8384 billion from the upfront payment due to the strategic alliance between Cullgen and Astellas Pharma Inc.

As a result, revenue and segment profit in the Pharmaceutical Segment were JPY18,272,865 thousand (up 65.4% year on year) and JPY5,915,025 thousand (up 643.5% year on year), respectively.

Medical Device Business

In the Medical Device Segment, revenue and segment income increased 32.7% to JPY2,275,030 thousand and 27.0% to JPY887,511 thousand, respectively, reflecting continued strong sales of BAB's mainstay bone transplantation-related products.

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

(Thousands of yen)

	First 3rd quarter of previous fiscal year	First 3rd quarter of fiscal year under review	Difference
Selling and general administrative expenses	△7,498,561	△9,556,455	△2,057,894
Personnel expenses	△2,733,706	△3,131,738	△398,033
Research and development expenses	△1,819,132	△1,776,530	42,601

Selling, general and administrative expenses for the first 3 quarters of the fiscal year under review increased 27.4% year on year to JPY9,556,455 thousand. This increase in selling, general and administrative expenses was primarily due to increases in personnel expenses in the Pharmaceutical Segment and costs to build a sales structure and marketing activity-related expenses.

R&D expenses for the first 3 quarters of the fiscal year under review were JPY1,776,530 thousand, down 2.3% year on year. This decrease in R&D expenses was primarily due to an increase in the capitalization of F351 R&D expenses at BC.

③ Finance income and costs

(Thousands of yen)

	First 3rd quarter of previous fiscal year	First 3rd quarter of fiscal year under review	Difference
Finance income	347,752	505,384	157,632
Financing cost	△618,870	△904,311	△285,441

Finance income

Finance income for the consolidated cumulative 3Q was JPY505,384 thousand (up 45.3% year on year). This increase in finance income was primarily due to an increase in interest income and foreign exchange gains.

Financing cost

During the first 3 quarters of the fiscal year under review, financial expenses amounted to JPY904,311 thousand (up 46.1% year on year). This increase in financing costs was primarily due to an increase in non-cash interest costs related to Cullgen financings.

(2) Financial Position

Consolidated Financial Position

(Thousands of yen)

	Previous consolidated fiscal year	End of 3rd quarter of the fiscal year under review	Difference
Total assets	33,906,981	48,468,006	14,561,025
Total liabilities	14,096,013	21,881,395	7,785,382
Total shareholders' equity	19,810,968	26,586,611	6,775,642

Total assets

Total assets at the end of the 3Q of the current fiscal year were JPY48,468,006 thousand (up 42.9% from the end of the previous fiscal year). This increase in assets was primarily due to an increase in cash and cash equivalents from Cullgen trade receivables and financing.

Total liabilities

Total liabilities at the end of the 3Q of the current fiscal year were JPY21,881,395 thousand (up 55.2% from the end of the previous fiscal year). This increase in debt was primarily due to the funding of Cullgen and the accretion of non-cash interest expense related to the funding.

Total shareholders' equity

Total capital for the 3Q of the current fiscal year was JPY26,586,611 thousand (up 34.2% from the end of the previous fiscal year). This was mainly due to an increase in retained earnings.

Consolidated cash flows

(Thousands of yen)

	First 3rd quarter of previous fiscal year	First 3rd quarter of fiscal year under review	Difference
Net cash provided by operating activities	△162,928	4,442,988	4,605,916
Cash Flows from investment activities	△2,909,505	△3,697,727	△788,221
Cash Flows from financing activities	△299,280	4,981,492	5,280,772

Net cash provided by operating activities

Net cash provided by operating activities for the first 3 quarters of the fiscal year under review was JPY4,442,988 thousand, compared with net cash used of JPY162,928 thousand in the same period of the previous fiscal year. This was mainly due to an increase in trade and other receivables of JPY1,974,714 thousand compared to quarterly profit before income taxes of JPY6,376,072 thousand.

Cash Flows from investment activities

Net cash used in investing activities for the first 3 quarters of the fiscal year under review was JPY3,697,727 thousand, compared with net cash used of JPY2,909,505 thousand in the same period of the previous fiscal year. Major expenditures were for the acquisition of long-term deposits in China and the acquisition of property, plant and equipment related to plant expansion.

Cash Flows from financing activities

Net cash provided by financing activities for the first 3 quarters of the fiscal year under review was JPY4,981,492 thousand, compared with net cash used in financing activities of JPY299,280 thousand in the same period of the previous fiscal year. The main source of proceeds was payments from non-controlling interests in connection with the financing of Cullgen.

(3) Issues to be Addressed in Business and Financial

There have been no significant changes in the Group's business and financial issues to be addressed during the 3Q of the fiscal year under review. In addition, there are no new issues.

(4) Research and Development

[Research activities]

Our group's drug discovery research aims to develop innovative new development candidate compounds (NCE), mainly in Cullgen. Cullgen is pursuing R&D to expand its drug discovery pipeline, which includes several new compounds targeting enzymes and non-enzymes for oncology, pain and autoimmune diseases.

As disclosed on June 15, 2023, Cullgen entered into a joint research and exclusive option contract with Astellas Pharma Inc. for the creation of innovative protein degradation derivatives. In this strategic alliance, the 2 companies will combine Cullgen's proprietary technological platform uSMITE™ that utilizes new E3 Ligand with the drug discovery capabilities of Astellas Pharma, with the aim of creating several protein-decomposition derivatives. Cullgen and Astellas Pharma will conduct joint research. Astellas Pharma will be responsible for development and commercialization. We are making steady progress in collaborating with Astellas Pharma Inc. in the United States, a lead program identified by Cullgen for the treatment of breast cancer and other solid cancers. This is a candidate compound for a decomposition inducer for cell-cycle protein.

[Development activities]

■ ETUARY® [Chinese: 依鲁替尼® , (Generic name: Pirfenidone)] by BC Diabetic Kidney Disease (DKD)

The Phase I clinical trial to expand the indication of ETUARY® to DKD has been completed, and an application for a Class 2 meeting (a technical meeting on clinical trials) has been submitted to the Center for Drug Evaluation (CDE) in China to determine the regulatory direction for the next phase of the clinical trial, and to discuss how to proceed.

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

Clinical trials for Phase III are ongoing to expand the indications of ETUARY® to two connective tissue disorders, systemic sclerosis (SSc-ILD) and dermatomyositis (DM-ILD). However, at present, priority is given to the clinical trials of F351.

Pneumoconiosis (PD)

Clinical trials are underway to expand the indications of ETUARY® in PD which entered Phase III in June 2022. Although the spread of COVID-19 in China at the end of 2022 to early 2023 had some impact, subject enrollment has resumed.

■ F351 (for liver fibrosis) (Generic Name: Hydronidone) by BC

F351 (Generic name: Hydronidone), a therapeutic drug for the treatment of liver fibrosis, is a key candidate in BC'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 derivative 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.

Following discussions with the CDE in China, F351 was designated by the NMPA in March 2021 as a breakthrough therapeutic drug for liver fibrosis. This has given us priority in our discussions with the CDE regarding F351 and has allowed us to proceed with clinical trials based on the results of those discussions. Subsequently, on July 29, 2021, an application for a Phase III clinical trial was approved in China, and a Phase III clinical trial was initiated in January 2022. The Phase III clinical trial has been making steady progress with the subject enrollment almost completed ahead of the target completion date of 2023 end.

While BC retains the rights to F351 in China, the ex-China rights to F351 including Japan, Australia, Canada, the United States and European countries have been transferred to CBIO (for details of this transaction, please refer to the timely disclosure of December 27, 2022, and the Q&A disclosed on December 30, 2022, and January 18, 2023).

CBIO anticipates filing an investigational new drug ("IND") application for the treatment of Metabolic Dysfunction Associated Steatohepatitis ("MASH") in the United States. There are currently no approved products for the treatment of MASH in the United States, Europe, or Japan.

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

BC'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).

As we disclosed on March 28, 2023, BC initiated a Phase II clinical trial for F573, has been making good progress.

■ CG001419 (TRK degrader) by Cullgen

The Group disclosed on August 9, 2022, that “China NMPA has approved GNI Group's Subsidiary Cullgen's IND for TRK Degradation Clinical Trial”. Cullgen received an IND approval from China’s NMPA (National Medical Products Administration) for CG001419, a tropomyosin receptor kinase (TRK) degrader for the treatment of solid tumors. CG001419 is a first-in-class, selective, potent oral targeted protein degrader for the treatment of advanced cancers with neurotrophic tyrosine receptor kinase (NTRK) gene / TRK protein aberrations, which have been identified in numerous solid tumors including non-small cell lung, breast, and pancreatic cancers.

Although the start of the clinical trial was delayed later than expected due to the outbreak of the COVID-19 in China in late 2022 and early 2023, as disclosed in July 2023, Cullgen started the Phase I/II clinical trial for the TRK degrader in China, which is their first clinical trial for humans. In addition, pre-clinical discussions with the United States Food and Drug Administration (FDA) are ongoing prior to a clinical trial in the United States.

3 [Significant Management Contracts]

(1) Subsidiary Berkeley Biologics LLC of our consolidated subsidiary Berkeley Advanced Biomaterials Inc. will acquire a portion of the orthobiologics business of Elutia Inc.

Contract Name	Asset Purchase Agreement
Name of the other party	Elutia Inc.
Country name	United States of America
Contract day	September 17, 2023
Contract period	No specific provisions
Contract contents	Within Elutia's orthobiologics business, the Company will prepay for the portion involved in contract manufacturing (human capital involved in contract manufacturing of orthobiologics, property, plant and equipment such as land, buildings and machinery and equipment, intangible assets such as software, and inventories) \$15 million plus contingent consideration of up to \$20 million to be paid to Elutia in cash over the next 5 years, depending on the degree of performance achievement.

Third [Status of the Filing Company]

1 [Status of Shares]

(1) [Total Number of Shares]

① [Total number of shares]

Type	Total number of authorized shares
Common stock	90,000,000
Total	90,000,000

② Issued Shares]

Type	Number of shares issued as of the end of the 3Q (As of September 30, 2023)	Number of shares issued as of the date of filing (shares) (November 14, 2023)	Name of a Listed Financial Instruments Exchange or Registered Authorized Financial Instruments Firms Association	Content
Common stock	47,514,843	47,514,843	Tokyo Stock Exchange Growth market	Share unit: 100 shares
Total	47,514,843	47,514,843	-	-

(NOTE) Number of shares issued as of the filing date do not include those issued upon exercise of subscription rights from November 1, 2023 to the filing date of this quarterly report.

(2) [Status of Stock Acquisition Rights]

① [Details of stock option plan]

(Resolution of the Board of Directors on July 20, 2023) (50th Stock Acquisition Rights)

Date of resolution	July 20, 2023
Classification and number of grantees	Director 7 Employees 4
Number of stock options (unit) ※	7,800
Type, description and number of shares subject to stock acquisition rights (shares)*	Common stock 780 thousand (Note 1)
Payment on exercise price of stock acquisition rights () ※	1216 (Note) 2 (Note) 3
Period for exercising subscription rights ※	From August 4, 2025 to August 4, 2035
Issue price for shares upon exercise of stock acquisition rights and appropriation to capital () ※	Issue price 1,216 Amount incorporated into capital 608
Exercise of stock acquisition rights*	<p>① Holders of Share Options may exercise the Allotted Share Options only if the operating income in our audited Consolidated Statement of Income for the year ended December 31, 2023 is equal to or greater than JPY1.4 billion. In addition, in the event that there is a material change in the concept of operating income to be referred to due to revisions to accounting standards, etc., we shall apply indices established by the Board of Directors in lieu of the above indices to the extent reasonable.</p> <p>② In cases where a holder of Share Options dies, the heirs of such holder of Share Options may exercise the Share Options.</p> <p>③ 1 stock acquisition right warrant may not be exercised in part.</p> <p>④ Prior to the finalization of the consolidated statement of income for the year ended December 31, 2023 described in ① above, (i) the share exchange agreement or the share transfer plan in which we become a wholly-owned subsidiary was approved by the shareholders (except in any case where new share acquisition rights similar to the Share Acquisition Rights are issued by the surviving company or our wholly-owned parent company), (ii) when all or substantially all of our assets are sold, or (iii) when a third party acquires shares equivalent to 50% of the voting rights of our shareholders, we notify the holders of the Share Acquisition Rights to that effect, and for 15 days after the notice is received. All stock acquisition rights that have not yet been exercised may be exercised.</p> <p>⑤ The terms and conditions for the exercise of other rights shall be governed by the provisions of the Share Option Allotment Agreement concluded between the Company and the holders of Share Options.</p> <p>⑥ Holders of Share Options shall not be required to be directors, auditors, or employees of Us or our Affiliated Companies at the time of exercise of Share Options.</p>
Items related to transfer of subscription rights ※	Option transfer conditions Approval of the Board of Directors is required for the transfer of any options.
Matters related to the issuance of stock acquisition rights associated with reorganization actions*	Not applicable.

※Details of the stock acquisition rights at the time of issuance (August 4, 2023) are shown below.

- (NOTE) 1. In cases where the value of assets to be contributed upon the exercise of Share Options should be adjusted, the number of shares subject to Share Options shall be adjusted as follows.

$$\text{Number of shares after adjustment} = \frac{\text{Number of shares before adjustment} \times \text{exercise price before adjustment}}{\text{Exercise price after the adjustment}}$$

The above adjustment of the number of shares subject to the stock acquisition rights shall be made only for the number of shares subject to the stock acquisition rights that have not been issued or exercised at the time when any of the events causing the adjustment occurs. In addition, if the calculation results in fractions less than 1 share, this shall be rounded up.

2. If we effect a stock split or reverse stock split after the date of allotment of the stock acquisition rights, the exercise price shall be adjusted according to the following formula, and fractions less than JPY1 as a result of the adjustment shall be rounded up.

$$\text{Adjusted exercise price} = \text{Exercise price before adjustment} \times \frac{1}{\text{Ratio of split (or consolidation)}}$$

3. If, after the allotment date, we issue new shares or dispose of treasury stock at a price below the market price of our common stock (excluding the cases where the issuance of new shares based on the exercise of subscription rights and the disposition of treasury stock through share exchange and the transfer of treasury stock through share exchange), the exercise price will be adjusted according to the following formula, and the fraction less than JPY1 due to the adjustment will be rounded up.

$$\text{Adjusted exercise price} = \text{Exercise price before adjustment} \times \frac{\text{Number of issued stocks} + \frac{\text{Number of newly issued shares} \times \text{Subscription price per share}}{\text{Market value per share before new issue}}}{\text{Number of shares outstanding} + \text{Number of newly issued shares}}$$

In the above formula, "number of shares already issued" refers to the number of shares issued related to our common stock less the number of treasury shares related to our common stock. In addition, when we dispose of treasury shares related to our common stock, "number of newly issued shares" refers to the "number of treasury shares to be disposed."

Furthermore, in addition to the foregoing, in the event that, after the date of allotment of stock acquisition right warrants, we merge with another company, effect a company split, or otherwise require an adjustment of the Exercise Price in accordance with such cases, we shall be entitled to make an appropriate adjustment of the Exercise Price to the extent reasonable.

(Resolution of the Board of Directors on August 28, 2023) (51st Stock Acquisition Rights)

Date of resolution	August 28, 2023
Classification and number of grantees	Executive Officers 1 Employees 2
Number of stock options (unit) ※	1,350
Type, description and number of shares subject to stock acquisition rights (shares)*	Common stock 135 thousand (Note 1)
Payment on exercise price of stock acquisition rights () ※	2095 (Note) 2 (Note) 3
Period for exercising subscription rights ※	From September 12, 2023 to September 12, 2028
Issue price for shares upon exercise of stock acquisition rights and appropriation to capital () ※	Issue price 2,095 Amount incorporated into capital 1,047.5
Exercise of stock acquisition rights*	<p>①The stock acquisition rights holders may exercise the stock acquisition rights allocated only if the number of IR meetings held for institutional investors in a single quarter reaches 15 or more times, as reported at our management meeting in any quarterly period ending 1 year from the date of issuance of the stock acquisition rights.</p> <p>②In cases where a holder of Share Options dies, the heirs of such holder of Share Options may exercise the Share Options.</p> <p>③1 stock acquisition right warrant may not be exercised in part.</p> <p>④Prior to the determination of the number of quarterly IR meetings for institutional investors described in ① above, (i) the share exchange agreement or the share transfer plan in which we become a wholly-owned subsidiary was approved by the shareholders (except in any case where new share acquisition rights similar to the Share Acquisition Rights are issued by the surviving company or our wholly-owned parent company), (ii) when all or substantially all of our assets are sold, or (iii) when a third party acquires shares equivalent to 50% of the voting rights of our shareholders, we notify the holders of the share acquisition rights and the share acquisition rights are allotted 15 days after the notice is received. All stock acquisition rights that have not yet been exercised may be exercised.</p> <p>⑤The terms and conditions for the exercise of other rights shall be governed by the provisions of the Share Option Allotment Agreement concluded between the Company and the holders of Share Options.</p> <p>⑥Holders of Share Options shall not be required to be directors, auditors, executive officers, or employees of the Company or any of its Affiliated Companies at the time of exercise of Share Options.</p>
Items related to transfer of subscription rights ※	Option transfer conditions Approval of the Board of Directors is required for the transfer of any options.
Matters related to the issuance of stock acquisition rights associated with reorganization actions*	Not applicable.

※Details of the stock acquisition rights at the time of issuance (September 12, 2023) are shown below.

- (NOTE) 1. In cases where the value of assets to be contributed upon the exercise of Share Options should be adjusted, the number of shares subject to Share Options shall be adjusted as follows.

$$\text{Number of shares after adjustment} = \frac{\text{Number of shares before adjustment} \times \text{exercise price before adjustment}}{\text{Exercise price after the adjustment}}$$

The above adjustment of the number of shares subject to the stock acquisition rights shall be made only for the number of shares subject to the stock acquisition rights that have not been issued or exercised at the time when any of the events causing the adjustment occurs. In addition, if the calculation results in fractions less than 1 share, this shall be rounded up.

2. If we effect a stock split or reverse stock split after the date of allotment of the stock acquisition rights, the exercise price shall be adjusted according to the following formula, and fractions less than JPY1 as a result of the adjustment shall be rounded up.

$$\text{Adjusted exercise price} = \text{Exercise price before adjustment} \times \frac{1}{\text{Ratio of split (or consolidation)}}$$

3. If, after the allotment date, we issue new shares or dispose of treasury stock at a price below the market price of our common stock (excluding the cases where the issuance of new shares based on the exercise of subscription rights and the disposition of treasury stock through share exchange and the transfer of treasury stock through share exchange), the exercise price will be adjusted according to the following formula, and the fraction less than JPY1 due to the adjustment will be rounded up.

$$\text{Adjusted exercise price} = \text{Exercise price before adjustment} \times \frac{\text{Number of issued stocks} + \frac{\text{Number of newly issued shares} \times \text{Subscription price per share}}{\text{Market value per share before new issue}}}{\text{Number of shares outstanding} + \text{Number of newly issued shares}}$$

In the above formula, "number of shares already issued" refers to the number of shares issued related to our common stock less the number of treasury shares related to our common stock. In addition, when we dispose of treasury shares related to our common stock, "number of newly issued shares" refers to the "number of treasury shares to be disposed."

Furthermore, in addition to the foregoing, in the event that, after the date of allotment of stock acquisition right warrants, we merge with another company, effect a company split, or otherwise require an adjustment of the Exercise Price in accordance with such cases, we shall be entitled to make an appropriate adjustment of the Exercise Price to the extent reasonable.

(Resolution of the Board of Directors on September 4, 2023) (52nd Stock Acquisition Rights)

Date of resolution	September 4, 2023
Classification and number of grantees	Former employees 1
Number of stock options (unit) ※	100
Type, description and number of shares subject to stock acquisition rights (shares)*	Common stock 10 thousand (Note 1)
Payment on exercise price of stock acquisition rights () ※	1699 (Note) 2 (Note) 3
Period for exercising subscription rights ※	From September 21, 2023 to September 20, 2025
Issue price for shares upon exercise of stock acquisition rights and appropriation to capital () ※	Issue price 1,699 Amount incorporated into capital 849.5
Exercise of stock acquisition rights*	①In cases where a holder of Share Options dies, the heir may exercise the Share Options only within 1 year after his/her death. ②1 stock acquisition right warrant may not be exercised in part. ③The terms and conditions for the exercise of other rights shall be governed by the provisions of the Share Option Grant Agreement concluded between the Company and the holders of Share Options.
Items related to transfer of subscription rights ※	Option transfer conditions Approval of the Board of Directors is required for the transfer of any options.
Matters related to the issuance of stock acquisition rights associated with reorganization actions*	Not applicable.

※Details of the stock acquisition rights at the time of issuance (September 20, 2023) are shown below.

(NOTE) 1. In cases where the value of assets to be contributed upon the exercise of Share Options should be adjusted, the number of shares subject to Share Options shall be adjusted as follows.

$$\text{Number of shares after adjustment} = \frac{\text{Number of shares before adjustment} \times \text{exercise price before adjustment}}{\text{Exercise price after the adjustment}}$$

The above adjustment of the number of shares subject to the stock acquisition rights shall be made only for the number of shares subject to the stock acquisition rights that have not been issued or exercised at the time when any of the events causing the adjustment occurs. In addition, if the calculation results in fractions less than 1 share, this shall be rounded down.

2. If we effect a stock split or reverse stock split after the date of allotment of the stock acquisition rights, the exercise price shall be adjusted according to the following formula, and fractions less than JPY1 as a result of the adjustment shall be rounded up.

$$\text{Adjusted exercise price} = \text{Exercise price before adjustment} \times \frac{1}{\text{Ratio of split (or consolidation)}}$$

3. If, after the allotment date, we issue new shares or dispose of treasury stock at a price below the market price of our common stock (excluding the cases where the issuance of new shares based on the exercise of subscription rights and the disposition of treasury stock through share exchange and the transfer of treasury stock through share exchange), the exercise price will be adjusted according to the following formula, and the fraction less than JPY1 due to the adjustment will be rounded up.

$$\text{Adjusted exercise price} = \text{Exercise price before adjustment} \times \frac{\text{Number of issued stocks} + \frac{\text{Number of newly issued shares} \times \text{Subscription price per share}}{\text{Market value per share before new issue}}}{\text{Number of shares outstanding} + \text{Number of newly issued shares}}$$

In the above formula, "number of shares already issued" refers to the number of shares issued related to our common stock less the number of treasury shares related to our common stock. In addition, when we dispose of treasury shares related to our common stock, "number of newly issued shares" refers to the "number of treasury shares to be disposed."

Furthermore, in addition to the foregoing, in the event that, after the date of allotment of stock acquisition right warrants, we merge with another company, effect a company split, or otherwise require an adjustment of the Exercise Price in accordance with such cases, we shall be entitled to make an appropriate adjustment of the Exercise Price to the extent reasonable.

② [Status of other stock acquisition rights]

Not applicable.



(3) [Status of Exercise of Bonds with Stock Acquisition Rights with Exercise Price Adjustment, etc.]

Not applicable.

(4) [Changes in the number of issued shares, capital stock, etc.]

Date	Number of issued shares Change(Shares)	Number of issued shares Balance Co., Ltd.	Change in common stock (thousand yen)	Common stock balance (thousand yen)	Additional paid-in capital Change (thousand yen)	Balance of additional paid-in capital (thousand yen)
July 1, 2023- September 30, 2023	27,000	47,514,843	13,840	10,913,100	13,840	10,873,100

(NOTE) Increase due to exercise of subscription rights to shares.

(5) [Major Shareholders]

This quarterly accounting period is the 3Q accounting period, so there are no items to be stated.

(6) [Status of voting rights]

"Status of voting rights" as of the end of the 3Q of the current fiscal year cannot be stated because the contents of the shareholder register cannot be confirmed. Therefore, the list of shareholders based on the immediately preceding record date (June 30, 2023) is presented.

① [Issued Shares]

As of September 30, 2023

Classification	Number of Options (shares)	Number of voting rights	Content
Non-voting stock	-	-	-
Shares with Restricted Voting Rights (Autologous Shares)	-	-	-
Shares with restricted voting rights (other)	-	-	-
Shares with full voting rights (autologous stock, etc.)	(Treasury stock held) Common stock 1,400	-	-
Shares with full voting rights (other)	Common stock 47,470,800	474,708	-
Number of shares less than 1 unit	Common stock 15,643	-	-
Number of issued shares	47,487,843	-	-
Voting rights of all shareholders	-	474,708	-

② [Treasury stock]

As of September 30, 2023

Name of owner	Address of the holder	Number of shares held in treasury (shares)	Number of shares held in other person's name (shares)	Total number of shares held (shares)	Percentage of Shares in Issue (%)
(Treasury stock held) GNI Group Ltd.	Nihonbashi-honcho, Chuo-ku, Tokyo 2-Chome 2-No 2	1,400	-	1,400	0.00
Total	-	1,400	-	1,400	0.00

2 [Status of officers]

(1) Directors' Status

Not applicable.

(2) Status of Executive Officers

① New corporate executive officers

Title	Name	Date of birth	Brief History		Term of Office	Ownership Number of shares (Thousands of shares)	
Executive Officers CFO	Toshiya Kitagawa	May 10, 1976	2000 2002 2003 2008 2009 2017 2019 2023 2023 2023	April April February October April April January March July October October	Japan Bond Trading Co., Ltd. Garban Totan Securities Co., Ltd. (currently ICAP Totan Securities Co., Ltd.) DealMax Co., Ltd. OAG Certified Public Tax Accountant Corporate New Business Manager Takara Leben Co., Ltd. Director, Executive Officer, General Manager of Corporate Planning Office Hoosiers Holdings Co., Ltd. General Manager, Group Strategy Office BASE Co., Ltd. President Eltes Co., Ltd. Deputy General Manager of Corporate Planning Division GNI Group Co., Ltd. CSO GNI Group Co., Ltd. CFO (present)	(NOTE)	-

(NOTE) This is the period from the closing of the Board of Directors meeting held on July 3, 2023 to the closing of the first meeting of the Board of Directors to be held after the closing of the Ordinary General Meeting of Shareholders for the fiscal year ended December 2023.

② Changes in Directors

New position	Former position	Name	Date of transfer
Director, Executive Officer and Deputy President	Director, Executive Officer and CFO	Kanichiro Suzuki	October 1, 2023
Executive Officer and CFO	Executive Officer and CSO	Toshiya Kitagawa	October 1, 2023

(3) Number of Directors and Female Employees after Transfers by Gender and Ratio of Female Employees

8 men and 1 woman (11.1% of all directors are women)

Fourth [Status of Accounting]

1. Preparation of Condensed Quarterly Consolidated Financial Statements

Our condensed quarterly consolidated financial statements have been prepared in accordance with the provisions of Article 93 of the Ordinance on Terminology, Forms and Preparation Methods of Quarterly Consolidated Financial Statements (Cabinet Office Ordinance No. 64 of 2007) in accordance with International Accounting Standards No. 34, "Interim Financial Reports."

2. Audit Certification

Pursuant to Article 193-2-1 of the Financial Instruments and Exchange Act, we have received a quarterly review by Taiyo LLC of our condensed consolidated financial statements for the 3Q (July 1, 2023 to September 30, 2023) and the third quarter (January 1, 2023 to September 30, 2023) of the current fiscal year.

1 [Condensed Quarterly Consolidated Financial Statements]

(1) [Condensed Quarterly Consolidated Statements of Financial Position]

		(Thousands of yen)	
	Notes Number	Previous consolidated fiscal year As of December 31, 2022	End of 3rd quarter of the fiscal year under review (As of September 30, 2023)
Assets			
Non-current assets			
Property, plant, and equipment		3,951,217	4,973,336
Right-of-use asset		755,167	723,570
Goodwill		6,047,721	6,774,046
Intangible assets		2,928,800	3,863,731
Investments in certain entities, which are accounted for on the equity method		622,476	755,823
Deferred tax assets		184,171	230,528
Other financial assets	6	2,270,162	4,445,657
Total non-current assets		<u>16,759,717</u>	<u>21,766,695</u>
Current assets			
Inventory		1,693,412	1,573,751
Trade and other receivables		3,122,463	5,410,007
Other financial assets	6	196,543	63,740
Other current assets		1,085,535	1,511,210
Cash and cash equivalents		11,049,310	18,142,601
Total current assets		<u>17,147,264</u>	<u>26,701,311</u>
Total assets		<u><u>33,906,981</u></u>	<u><u>48,468,006</u></u>
LIABILITIES AND SHAREHOLDERS' EQUITY			
Non-current liability			
Lease liabilities		157,744	83,808
Deferred tax liabilities		546,790	724,731
Other financial liabilities	6	9,706,958	15,908,122
non current current liability		181,027	178,357
Total non-current liabilities		<u>10,592,520</u>	<u>16,895,018</u>
Current Liabilities			
Trade and other payables		949,612	759,871
Borrowings	6	200,000	1,300,000
Lease liabilities		179,611	186,962
Accrued income taxes		1,179,254	1,543,898
Other financial liabilities	6	7,225	7,069
Other current liability		987,788	1,188,574
Total current liabilities		<u>3,503,492</u>	<u>4,986,377</u>
Total liabilities		<u><u>14,096,013</u></u>	<u><u>21,881,395</u></u>
Capital			
Common stock	10	10,893,070	10,912,241
Capital surplus	9,10	6,233,386	5,500,673
Treasury stock		△756	△10,147
Retained earnings		696,360	2,909,635
Other components of equity	9	3,147,631	4,907,710
Equity attributable to parent owners (total)		<u>20,969,692</u>	<u>24,220,114</u>
Non-controlling interests	9	△1,158,724	2,366,497
Total shareholders' equity		<u>19,810,968</u>	<u>26,586,611</u>
Total shareholders' equity and liabilities		<u><u>33,906,981</u></u>	<u><u>48,468,006</u></u>

(2) [Condensed Quarterly Consolidated Statements of Income and Condensed Quarterly Consolidated Statements of Comprehensive Income]

[Condensed Quarterly Consolidated Statements of Income]

[Cumulative 3Q]

(Thousands of yen)

	Notes Number	First 3rd quarter of previous fiscal year (January 1, 2022 To September 30, 2022)	First 3rd quarter of fiscal year under review (January 1, 2023 To September 30, 2023)
Revenue	8	12,761,031	20,547,895
Cost of sales		△1,907,239	△2,369,420
Gross profit		10,853,792	18,178,475
Selling and general administrative expenses		△7,498,561	△9,556,455
Research and development expenses		△1,819,132	△1,776,530
Other income		82,623	358,417
Other expenses		△124,524	△401,369
Operating income		1,494,197	6,802,536
Finance income		347,752	505,384
Financing cost		△618,870	△904,311
Equity in losses of affiliates		-	△27,537
Quarterly profit before tax		1,223,079	6,376,072
Corporate income tax expenses		△898,662	△1,571,575
Quarterly profit		324,416	4,804,496
Quarterly profit attributable to			
Owners of the parent		1,076,065	2,213,274
Non-controlling interests		△751,649	2,591,222
Quarterly earnings per share			
Basic quarterly earnings per share (yen)	7	22.67	46.61
Diluted quarterly earnings per share (yen)	7	22.46	46.13

		(Thousands of yen)	
	Notes Number	3Q of the previous fiscal year (July 1, 2022 To September 30, 2022)	End of 3rd quarter of the fiscal year under review (July 1, 2023 To September 30, 2023)
Revenue		4,606,213	6,451,350
Cost of sales		Δ 772,584	Δ 1,028,205
Gross profit		3,833,629	5,423,144
Selling and general administrative expenses		Δ 2,732,811	Δ 3,377,271
Research and development expenses		Δ 729,592	Δ 523,471
Other income		28,243	72,236
Other expenses		90,059	Δ 268,577
Operating income		489,529	1,326,061
Finance income		171,977	198,860
Financing cost		Δ 228,815	Δ 365,273
Equity in earnings of affiliates		-	98,463
Quarterly profit before tax		432,690	1,258,111
Corporate income tax expenses		Δ 306,193	Δ 467,688
Quarterly profit		126,497	790,422
Quarterly profit attributable to			
Owners of the parent		399,618	554,468
Non-controlling interests		Δ 273,121	235,953
Quarterly earnings per share			
Basic quarterly earnings per share (yen)	7	8.42	11.68
Diluted quarterly earnings per share (yen)	7	8.28	11.33

[Condensed Quarterly Consolidated Statement of Comprehensive Income]

[Cumulative 3Q]

		(Thousands of yen)	
	Notes Number	First 3rd quarter of previous fiscal year (January 1, 2022 To September 30, 2022)	First 3rd quarter of fiscal year under review (January 1, 2023 To September 30, 2023)
Quarterly profit		324,416	4,804,496
Other comprehensive income			
Items that may be reclassified subsequently to profit or loss			
Exchange differences on translation of foreign operations		2,210,663	1,843,782
Share of other comprehensive income of entities accounted for using equity method		-	13,025
Total other comprehensive income		2,210,663	1,856,807
Total quarterly comprehensive income		2,535,079	6,661,304
Quarterly comprehensive income attributable to			
Owners of the parent		3,833,451	3,907,869
Non-controlling interests		△1,298,371	2,753,434

		(Thousands of yen)	
	Notes Number	3Q of the previous fiscal year (July 1, 2022 To September 30, 2022)	End of 3rd quarter of the fiscal year under review (July 1, 2023 To September 30, 2023)
Quarterly profit		126,497	790,422
Other comprehensive income			
Items that may be reclassified subsequently to profit or loss			
Exchange differences on translation of foreign operations		74,045	946,432
Share of other comprehensive income of entities accounted for using equity method		-	8,099
Total other comprehensive income		<u>74,045</u>	<u>954,532</u>
Total quarterly comprehensive income		<u>200,542</u>	<u>1,744,954</u>
Quarterly comprehensive income attributable to			
Owners of the parent		814,918	1,148,216
Non-controlling interests		△614,376	596,738

(3) [Condensed Quarterly Consolidated Statement of Changes in Equity]

Cumulative 3Q of the Previous Fiscal Year (From January 1, 2022 to September 30, 2022)

(Thousands of yen)

	Notes Number	Equity attributable to owners of the parent company						Other components of equity		Total
		Common stock	Capital surplus	Treasury stock	Retained earnings	Stock acquisition right	Exchange differences on translation of foreign operations			
Balance at January 1, 2022		10,884,332	6,224,649	△645	307,535	543,445	900,992	1,444,437		
Quarterly profit		-	-	-	1,076,065	-	-	-		
Other comprehensive income		-	-	-	-	-	2,757,385	2,757,385		
Total quarterly comprehensive income		-	-	-	1,076,065	-	2,757,385	2,757,385		
Issuance of new shares	10	6,858	6,858	-	-	-	-	-		
Share-based payment transactions		-	-	-	-	200,651	-	200,651		
Stock- issuing expense	10	-	△26	-	-	-	-	-		
Total transactions with owners		6,858	6,832	-	-	200,651	-	200,651		
Balance at September 30, 2022		10,891,191	6,231,481	△645	1,383,600	744,097	3,658,377	4,402,474		

	Notes Number	Equity attributable to owners of the parent company		Total shareholders' equity
		Total	Non-controlling interests	
Balance at January 1, 2022		18,860,309	405,936	19,266,246
Quarterly profit		1,076,065	△751,649	324,416
Other comprehensive income		2,757,385	△546,722	2,210,663
Total quarterly comprehensive income		3,833,451	△1,298,371	2,535,079
Issuance of new shares	10	13,717	-	13,717
Share-based payment transactions		200,651	-	200,651
Stock- issuing expense	10	△26	-	△26
Total transactions with owners		214,342	-	214,342
Balance at September 30, 2022		22,908,103	△892,434	22,015,668

3Q (January 1, 2023-September 30, 2023)

(Thousands of yen)

	Notes Number	Equity attributable to owners of the parent company						Other components of equity	
		Common stock	Capital surplus	Treasury stock	Retained earnings	Stock acquisition right	Exchange differences on translation of foreign operations	Total	
Balance at January 1, 2023		10,893,070	6,233,386	△756	696,360	824,192	2,323,439	3,147,631	
Quarterly profit		-	-	-	2,213,274	-	-	-	
Other comprehensive income		-	-	-	-	-	1,694,595	1,694,595	
Total quarterly comprehensive income		-	-	-	2,213,274	-	1,694,595	1,694,595	
Change in ownership interest in a controlled subsidiary	9	-	△751,883	-	-	-	△19,903	△19,903	
Issuance of new shares	10	19,171	19,171	-	-	△176	-	△176	
Share Option Issue		-	-	-	-	5,127	-	5,127	
Share-based payment transactions		-	-	-	-	106,374	-	106,374	
Cost of issuing stock acquisition rights		-	-	-	-	△4,213	-	△4,213	
Invalidation of Share Options		-	-	-	-	△21,725	-	△21,725	
Purchase of treasury stock		-	-	△9,390	-	-	-	-	
Total transactions with owners		19,171	△732,712	△9,390	-	85,386	△19,903	65,483	
Balance at September 30, 2023		10,912,241	5,500,673	△10,147	2,909,635	909,579	3,998,131	4,907,710	

	Notes Number	Equity attributable to owners of the parent company		
		Total	Non-controlling interests	Total shareholders' equity
Balance at January 1, 2023		20,969,692	△1,158,724	19,810,968
Quarterly profit		2,213,274	2,591,222	4,804,496
Other comprehensive income		1,694,595	162,211	1,856,807
Total quarterly comprehensive income		3,907,869	2,753,434	6,661,304
Change in ownership interest in a controlled subsidiary	9	△771,786	771,786	-
Issuance of new shares	10	38,165	-	38,165
Share Option Issue		5,127	-	5,127
Share-based payment transactions		106,374	-	106,374
Cost of issuing stock acquisition rights		△4,213	-	△4,213
Invalidation of Share Options		△21,725	-	△21,725
Purchase of treasury stock		△9,390	-	△9,390
Total transactions with owners		△657,448	771,786	114,338
Balance at September 30, 2023		24,220,114	2,366,497	26,586,611

(4) [Condensed Quarterly Consolidated Statements of Cash Flows]

		(Thousands of yen)	
	Notes Number	First 3rd quarter of previous fiscal year (January 1, 2022 To September 30, 2022)	First 3rd quarter of fiscal year under review (January 1, 2023 To September 30, 2023)
Net cash provided by operating activities			
Quarterly profit before tax		1,223,079	6,376,072
Depreciation		388,148	423,733
Decrease (increase) in trade and other receivables		△940,488	△1,974,714
Increase (decrease) in trade and other payables		122,325	△256,652
Decrease (increase) in inventory		△117,673	260,964
Increase (decrease) in accrued bonuses		11,549	26,495
Finance income and costs		540,127	675,928
Others		△392,645	△18,663
Subtotal		834,423	5,513,164
Interest received		40,229	126,827
Interest paid		△9,568	△16,992
Income taxes paid		△1,028,013	△1,180,010
Net cash provided by operating activities		△162,928	4,442,988
Cash Flows from investment activities			
Decrease in time deposits		△1,159,200	△1,765,800
Purchases of property, plant and equipment		△723,140	△1,041,104
Proceeds from sales of property, plant and equipment		-	1,927
Purchase of intangible assets	11	△441,652	△694,565
Purchases of investment securities		△589,252	△139,128
Increase in leasehold and security deposits		△266	△3,753
Proceeds from decrease in guarantee deposits and lease deposits		449	-
Lending of loans receivable		-	△58,860
Collection of loans receivable		3,557	3,557
Net cash used in investing activities		△2,909,505	△3,697,727
Cash Flows from financing activities			
Increase (decrease) in short-term borrowings		△200,000	1,100,000
Proceeds from share issuance to non-controlling interests		-	4,008,959
Proceeds from exercise of stock acquisition rights	10	-	27,504
Proceeds from issuance of stock acquisition rights		-	357
Repayments of lease liabilities		△98,520	△152,451
Purchase of treasury stock		-	△38
Others		△760	△2,838
Net cash used in financing activities		△299,280	4,981,492
Translation adjustments on cash and Cash Equivalents		1,741,793	1,366,537
Net increase (decrease) in cash and cash equivalents		△1,629,920	7,093,291
The beginning balances of cash and Cash Equivalents		14,352,133	11,049,310
Period-end balance of cash and cash equivalents		12,722,213	18,142,601

1. Reporting company

We are a corporation domiciled in Japan. The address and principal place of business of the registered office is 2-2-2, Nihonbashi-honcho, Chuo-ku, Tokyo. Our Group is engaged in the pharmaceutical-related business and the medical device-related business.

Our consolidated subsidiaries BC, Shanghai Genomics Co., Ltd., GNI Hong Kong Limited, Shanghai Genomics Technology Co., Ltd., Cullgen (Shanghai), Inc. and Shanghai Leaf International Trading Co., Ltd. are engaged in pharmaceutical-related businesses, including clinical trials in China, drug development and manufacturing and sales, antibody manufacturing and sales, and contract research for drug discovery. In the United States, GNI USA, Inc. and Cullgen Inc., which are consolidated subsidiaries, develop drugs.

Our consolidated subsidiaries, Berkeley Advanced Biomaterials LLC and Micren Healthcare Co., Ltd., provide biomaterials, medical device selection manufacturers and distributors (DMAH) and clinical trial domestic administrator (ICC) services.

Our Condensed Quarterly Consolidated Financial Statements for the period ended September 30, 2023 were approved by Toshiya Kitagawa, Executive Officer and CFO, and Ying Luo, Director, Representative Executive Officer, President and CEO, on November 14, 2023.

2. Basis of preparation

(1) Matters to the effect that they comply with IFRS

The condensed quarterly consolidated financial statements of our group have been prepared in accordance with International Accounting Standards No. 34, "Interim Financial Reporting."

The provisions of Article 93 of the Ordinance on Terminology, Forms, and Preparation Methods of Quarterly Consolidated Financial Statements (Cabinet Office Ordinance No. 64 of 2007) have been applied to our Group as they satisfy the requirements of "Designated International Accounting Standards Designated Companies" set forth in Article 1-2 of the said Ordinance.

This condensed quarterly consolidated financial statements do not include all of the information required by the annual consolidated financial statements and therefore should be used in conjunction with our consolidated financial statements for the year ended December 31, 2022.

(2) Functional and Presentation Currencies

The condensed quarterly consolidated financial statements of our group show the Japanese yen, which is our functional currency, as the presentation currency, and amounts of less than JPY1 thousand have been rounded down.

3. Critical Accounting Policies

The accounting policies applied in the condensed quarterly consolidated financial statements are the same as the accounting policies applied in the consolidated financial statements for the previous fiscal year.

Income tax expense for the 3Q of the current fiscal year is calculated based on the estimated annual effective tax rate.

The standards and interpretations that our group has applied since the 1Q of the consolidated fiscal year are as follows.

IFRS		Outline of New Establishment and Revision
IAS No. 1	Presentation of Financial Statements	Amendments requiring disclosure of critical accounting policies rather than critical accounting policies
IAS No. 8	Changes in accounting policies, accounting estimates and errors	Clarifying the distinction between accounting policies and accounting estimates
IAS No. 12	Corporate income tax	Clarified accounting for deferred taxes on lease and abandonment obligations

The adoption of the aforementioned pronouncements did not have a material impact on the condensed quarterly consolidated financial statements.

4. Significant accounting estimates and judgments involving estimates

The preparation of the condensed quarterly consolidated financial statements in conformity with IFRS requires management to make judgments, pro formas and assumptions that affect the application of accounting policies and the reported amounts of assets, liabilities, revenues and expenses. Actual results may differ from these estimates.

Judgments, pro formas and underlying assumptions are continually reviewed. The impact of revisions to accounting estimates is recognized in the period in which the estimates are revised and in future periods.

Judgments and estimates that have a material impact on the amounts shown in the Group's condensed quarterly consolidated financial statements are, in principle, the same as the consolidated financial statements for the previous fiscal year.

5. Business Segment

(1) The outline of any Reporting Segment

The reportable segments of our group are the constituent units of our group for which separate financial information is available and for which the Board of Directors conducts periodic reviews to determine the allocation of management resources and evaluate business performance.

Our Group is engaged in the pharmaceutical business, which is the drug discovery and manufacturing and sales business, and the medical device business. The drugs segment conducts research and development, manufacturing, sales, and contract research for pharmaceuticals. The Medical Devices segment conducts research and development, manufacturing, and sales of medical devices, including biomaterials.

The main products of each reportable segment are as follows.

Reportable Segments	Company Name	Main Products
Pharmaceutical Business	GNI Group Ltd., Beijing Continent Pharmaceutical Co., Ltd, Shanghai Genomics Co., Ltd., GNI Hong Kong Limited, Shanghai Genomics Technology Co., Ltd., Cullgen (Shanghai), Inc., GNI USA, Inc., Cullgen Inc., Shanghai RUI FU International Trading Co., Ltd.	ETUARY®, drug development, other drugs, reagents
Medical Device Business	Berkeley Advanced Biomaterials LLC and Micren Healthcare Co., Ltd.	Biomaterials, Selected Medical Device Marketers (DMAH) and Clinical Trial Domestic Manager (ICC) Servicing

(2) Revenue and profit/loss of reportable segments

The reportable segment information of our group is as follows.

Cumulative 3Q of the Previous Fiscal Year (From January 1, 2022 to September 30, 2022)

	Reportable Segments			Adjusted amount	Consolidated
	Pharmaceutical Business	Medical Device Business	Total		
Revenue					
(1)Revenue from customers	11,046,069	1,714,961	12,761,031	-	12,761,031
(2)Intersegment revenue or transfers	-	37,620	37,620	△37,620	-
Total	11,046,069	1,752,582	12,798,651	△37,620	12,761,031
Segment profit	795,584	698,613	1,494,197	-	1,494,197
				Finance income	347,752
				Financing cost	△618,870
				Quarterly profit before tax	1,223,079

(NOTE) 1. Revenue adjustments represent inter-segment revenue.

2.Segment income uses operating income in the condensed quarterly consolidated statements of income.

3Q (January 1, 2023-September 30, 2023)

	Reportable Segments			Adjusted amount	Consolidated
	Pharmaceutical Business	Medical Device Business	Total		
Revenue					0
(1)Revenue from customers	18,272,865	2,275,030	20,547,895	-	20,547,895
(2)Intersegment revenue or transfers	-	23,754	23,754	△23,754	-
Total	18,272,865	2,298,784	20,571,650	△23,754	20,547,895
Segment profit	5,915,025	887,511	6,802,536	-	6,802,536
Finance income					505,384
				Financing cost	△904,311
				Equity in losses of affiliates	△27,537
				Quarterly profit before tax	6,376,072

(NOTE) 1. Revenue adjustments represent inter-segment revenue.

2.Segment income uses operating income in the condensed quarterly consolidated statements of income.

6. Fair value of financial instruments

(1) Fair value of financial instruments

The fair values of financial assets and liabilities and their carrying amounts in the condensed quarterly consolidated statements of financial position are as follows:

	(Thousands of yen)			
	End of the previous consolidated fiscal term As of December 31, 2022		End of 3rd quarter of the fiscal year under review (As of September 30, 2023)	
	Book value	Fair value	Book value	Fair value
Financial assets				
Time deposits (over 3 months)	191,799	191,799	-	-
Lease deposits	63,427	60,701	76,589	74,058
Loans receivable	4,743	4,743	62,565	62,565
Long-term deposits	977,311	977,311	3,164,929	3,164,929
Investments in capital	1,229,423	1,229,423	1,205,313	1,205,313
Total	2,466,705	2,463,979	4,509,397	4,506,867
Financial Liabilities				
Borrowings	200,000	200,000	1,300,000	1,300,000
Guarantee deposits received	7,225	7,225	7,069	7,069
Other financial liabilities (preferred stock)	9,694,374	9,694,374	15,891,097	15,891,097
Other financial liabilities (stock acquisition rights)	12,583	12,583	17,024	17,024
Total	9,914,183	9,914,183	17,215,191	17,215,191

(2) Fair Value Measurements

The fair values of financial assets and financial liabilities are calculated as follows:

(Time deposits over 3 months)

Time deposits (more than 3 months) have maturities of 1 year or less and are short-term, and their fair values approximate their carrying values.

(Lease and guarantee deposits)

The fair value of leasehold and security deposits is estimated by classifying them by contract and discounting them at a rate that considers credit risk to an appropriate index, such as the yield on government bonds, depending on the contract term.

(Loans)

The fair value of loans approximates their carrying amounts due to their short maturities.

(Long-term deposits)

For long-term deposits, there is no difference between the initial recognition fair value and the amortized cost and transaction value using the effective interest method, and the carrying amount approximates fair value.

(Investments in capital)

Equity investments are primarily equity interests in unlisted companies and are valued at fair value using a combination of the comparable company method and an option valuation model. Unobservable inputs such as enterprise value are also used in this valuation model. The Company used enterprise value conversions ranging from-12.7% to-52.7% depending on comparable companies to measure fair value.

(Borrowings)

The fair value of short-term borrowings approximates their carrying amounts due to their short-term maturities.

(Guarantee deposits received)

The fair value of guarantee deposits received is estimated by discounting the future cash flows at an interest rate calculated by adding credit risk to an appropriate index, such as the yield on government bonds, depending on the period until the maturity date. The fair value of guarantee deposits received approximates their carrying amount due to their short maturities.

(Other financial liabilities (preferred stock))

Other financial liabilities (preferred stock) are estimated at fair value using a method in which the face value of the investment is discounted at the rate based on the contract. This valuation methodology utilizes unobservable inputs such as discount rates. The Company used a 10% discount rate to measure fair value.

(Other financial liabilities (stock acquisition rights))

Other financial liabilities (warrants) are estimated at fair value using a Monte Carlo simulation. In this valuation method, unobservable inputs such as discount rates are used. A discount rate of 0.1% was used to measure fair value.

(Other financial instruments)

The fair values of financial instruments other than those listed above approximate their carrying amounts because of their short-term nature.

(3) Fair value hierarchy

The fair value of financial instruments is based on the inputs used to measure fair value, and the respective levels are classified as follows:

Level 1: Fair values measured by quoted market prices (unadjusted) in active markets for identical assets or liabilities

Level 2: Fair values measured using directly or indirectly observable measures other than Level 1

Level 3: Fair values measured using significant unobservable measures

If the Company uses multiple inputs to measure fair value, the Company determines the level of fair value based on the lowest level input that is significant to the fair value measurement in its entirety. Transfers between levels of the fair value hierarchy are recognized as they occur as of the beginning of each quarter. There were no transfers between Level 1 and Level 2 during the previous fiscal year or the current fiscal year.

Previous fiscal year (As of December 31, 2022)

	Level 1	Level 2	Level 3	(Thousands of yen) Total
Financial assets				
Financial assets measured at amortized cost				
Time deposits (over 3 months)	-	191,799	-	191,799
Lease deposits	-	60,701	-	60,701
Loans receivable	-	4,743	-	4,743
Long-term deposits	-	977,311	-	977,311
Financial assets measured at fair value through profit or loss				
Investments in capital	-	-	1,229,423	1,229,423
Total	-	1,234,555	1,229,423	2,463,979
Financial Liabilities				
Financial liabilities measured at amortized cost				
Borrowings	-	200,000	-	200,000
Guarantee deposits received	-	7,225	-	7,225
Other financial liabilities (preferred) Stocks)	-	-	9,694,374	9,694,374
Other financial liabilities (new shares)				
Subscription Rights	-	-	12,583	12,583
Total	-	207,225	9,706,958	9,914,183

Current 3Q (As of September 30, 2023)

	Level 1	Level 2	Level 3	(Thousands of yen) Total
Financial assets				
Financial assets measured at amortized cost				
Lease deposits	-	74,058	-	74,058
Loans receivable	-	62,565	-	62,565
Long-term deposits	-	3,164,929	-	3,164,929
Financial assets measured at fair value through profit or loss				
Investments in capital	-	-	1,205,313	1,205,313
Total	-	3,301,553	1,205,313	4,506,867
Financial Liabilities				
Financial liabilities measured at amortized cost				
Borrowings	-	1,300,000	-	1,300,000
Guarantee deposits received	-	7,069	-	7,069
Other financial liabilities (preferred) Stocks)	-	-	15,891,097	15,891,097
Other financial liabilities (new shares)				
Subscription Rights	-	-	17,024	17,024
Total	-	1,307,069	15,908,122	17,215,191

(NOTE) For financial instruments classified as Level 3, an external valuation specialist or appropriate valuation specialist performs an evaluation and analysis of the results of the evaluation in accordance with the valuation policies and procedures approved by the appropriate person. The evaluation results are reviewed and approved by the appropriate authority.

For equity investments classified as Level 3, fair value is increased (decreased) due to an increase (decrease) in enterprise value. For other financial liabilities (preferred stock) classified as Level 3, the fair value is increased (decreased) due to a decrease (increase) in the discount rate. The increase or decrease in the fair value that is expected if the unobservable inputs are changed to reasonably possible alternative assumptions is not material.

(4) Reconciliation of financial instruments classified as Level 3 from the beginning of the period to the ending balance Financial assets classified as Level 3

	First 3rd quarter of previous fiscal year (January 1, 2022 To September 30, 2022)	(Thousands of yen) First 3rd quarter of fiscal year under review (January 1, 2023 To September 30, 2023)
Balance at beginning of year	887,694	1,229,423
Total gains and losses	△11,706	△161,167
Net income (loss)	△11,706	△161,167
Purchase	627,147	-
Effect of exchange rate	209,889	137,057
Ending balance	1,713,024	1,205,313

Financial liabilities classified as Level 3

	First 3rd quarter of previous fiscal year (January 1, 2022 To September 30, 2022)	(Thousands of yen) First 3rd quarter of fiscal year under review (January 1, 2023 To September 30, 2023)
Balance at beginning of year	7,539,814	9,706,958
Effect of exchange rate	1,948,701	1,233,165
Other (preferred stock)	957,276	4,963,557
Other (stock acquisition rights)	△4,194	4,441
Ending balance	10,441,597	15,908,122

Quarterly earnings per share of 7.1

(1) Basic quarterly earnings per share

Basic earnings per share for the 3Q of each fiscal year and the basis for calculating such earnings are as follows.

	First 3rd quarter of previous fiscal year (January 1, 2022 To September 30, 2022)	First 3rd quarter of fiscal year under review (January 1, 2023 To September 30, 2023)
Quarterly profit attributable to owners of the parent (thousand yen)	1,076,065	2,213,274
Average number of shares of common stock outstanding during the period (shares)	47,469,747	47,487,233
Basic quarterly earnings per share (yen)	22.67	46.61

Basic earnings per share for the 3Q of each fiscal year and the basis for calculating such earnings are as follows.

	3Q of the previous fiscal year (July 1, 2022 To September 30, 2022)	End of 3rd quarter of the fiscal year under review (July 1, 2023 To September 30, 2023)
Quarterly profit attributable to owners of the parent (thousand yen)	399,618	554,468
Average number of shares of common stock outstanding during the period (shares)	47,485,718	47,488,778
Basic quarterly earnings per share (yen)	8.42	11.68

(2) Quarterly diluted earnings per share

Diluted earnings per share for the 3Q of each fiscal year and the basis for calculating such earnings are as follows:

	First 3rd quarter of previous fiscal year (January 1, 2022 To September 30, 2022)	First 3rd quarter of fiscal year under review (January 1, 2023 To September 30, 2023)
Quarterly profit attributable to owners of the parent (thousand yen)	1,076,065	2,213,274
Average number of shares of common stock outstanding during the period (shares)	47,469,747	47,487,233
Adjustment for the effect of dilution:		
Stock Options (shares)	435,126	487,690
Weighted-average number of shares outstanding during the period after dilutive effect (shares)	47,904,873	47,974,923
Diluted quarterly earnings per share (yen)	22.46	46.13

Diluted earnings per share for the 3Q of each fiscal year and the calculation basis are as follows:

	3Q of the previous fiscal year (July 1, 2022 To September 30, 2022)	End of 3rd quarter of the fiscal year under review (July 1, 2023 To September 30, 2023)
Quarterly profit attributable to owners of the parent (thousand yen)	399,618	554,468
Average number of shares of common stock outstanding during the period (shares)	47,485,718	47,488,778
Adjustment for the effect of dilution:		
Stock Options (shares)	758,725	1,447,562
Weighted-average number of shares outstanding during the period after dilutive effect (shares)	48,244,443	48,936,340
Diluted quarterly earnings per share (yen)	8.28	11.33

8. Revenue

Our group consists of tissues based on the Pharmaceuticals Business and the Medical Device Business. Revenues recorded in these businesses are presented as revenue, as our Board of Directors regularly examines them in order to determine the allocation of management resources and evaluate business performance. Revenue is broken down by region based on the location of the customer.

The relationship between these broken down revenues and the revenues of each reportable segment is as follows:

Cumulative 3Q of the Previous Fiscal Year (From January 1, 2022 to September 30, 2022)

	Pharmaceutical Business	Medical Device Business	(Thousands of yen) Total
Japan	15,893	-	15,893
China	10,990,066	-	10,990,066
USA	40,109	1,714,961	1,755,071
Total	<u>11,046,069</u>	<u>1,714,961</u>	<u>12,761,031</u>

In the drugs business, the Group conducts research and development, manufacturing, sales, and contract research for pharmaceuticals. Its main customers include domestic and overseas wholesalers, medical institutions, and research institutions.

The Medical Device Business conducts research and development, manufacturing and sales of medical equipment, including biomaterials. Its main customers include domestic and overseas wholesalers and medical institutions.

Revenues from the sale of products in these businesses are accounted for in accordance with the same accounting policies applied in the consolidated financial statements for the previous fiscal year.

3Q (January 1, 2023-September 30, 2023)

	Pharmaceutical Business	Medical Device Business	(Thousands of yen) Total
Japan	14,868	141,309	156,177
China	15,322,187	-	15,322,187
USA	2,935,810	2,133,720	5,069,530
Total	<u>18,272,865</u>	<u>2,275,030</u>	<u>20,547,895</u>

In the drugs business, the Group conducts research and development, manufacturing, sales, and contract research for pharmaceuticals. Its main customers include domestic and overseas wholesalers, medical institutions, and research institutions.

The Medical Device Business conducts research and development, manufacturing and sales of medical equipment, including biomaterials. Its main customers include domestic and overseas wholesalers and medical institutions.

Revenues from the sale of products in these businesses are accounted for in accordance with the same accounting policies applied in the consolidated financial statements for the previous fiscal year.

9. Changes in interests in subsidiaries

There were no relevant items in the previous consolidated cumulative 3Q.

During the first 3 quarters of the fiscal year, Cullgen received Series C capital expenditures totaling \$35 million from several global venture capital firms, including GNI USA, Inc ("GNI USA"). The amount invested in the Series C was \$29 million and \$6 million from several global venture capital firms and GNI USA, respectively. Cullgen has issued preferred stock for such Series C Investments. As these preferred GNI USA are classified as debt instruments, the Company recorded a total of JPY4,337,819 thousand in other financial liabilities (non-current), excluding intercompany investments. In addition, we invested \$5 million from GNI USA as additional capital in Cullgen to further strengthen and expand our drug discovery business. As a result of the above series of investments, non-controlling interests increased by ¥771,786 thousand, and foreign currency translation adjustments of capital surplus and foreign operations decreased by ¥751,883 thousand and JPY19,903 thousand, respectively.

10. Shareholders' equity and other equity items

(1) Issuance of new shares upon exercise of subscription rights to shares

There were no relevant items in the previous consolidated cumulative 3Q.

During the consolidated cumulative 3Q under review, the Company issued new shares upon the exercise of subscription rights to shares, and JPY13,840 thousand was transferred to common stock and JPY13,840 thousand to capital surplus.

(2) Issuance of new shares in connection with the introduction of restricted stock compensation plans

During the 3Q of the previous fiscal year, the Board of Directors resolved to introduce a restricted stock compensation system at the Board of Directors' meeting held on June 16, 2022, and issued new shares on July 4. Accordingly, JPY6,858 thousand was allocated to common stock and capital surplus, respectively. Issuance costs of JPY26 thousand associated with the issuance of new shares were adjusted by capital surplus.

During the 3Q of the current fiscal year, JPY5,330 thousand has been included in common stock and JPY5,330 thousand has been included in capital surplus as a result of the grant of restricted shares in the previous fiscal year.

11. Purchase of intangible assets

Acquisition of intangible assets of JPY441,652 thousand in the 3Q of the previous fiscal year was mainly due to the acquisition of development costs that can be recognized as assets by the consolidated subsidiary BC.

Acquisition of intangible assets of JPY694,565 thousand in the 3Q of the current fiscal year was mainly due to the acquisition of development costs that can be recognized as assets by the consolidated subsidiary BC.

12. Significant Subsequent Events

(Business Combination through Acquisition)

At a meeting of the Board of Directors held on December 27, 2022, we resolved to enter into a company combination agreement with CBIO (now Gyre Therapeutics, Inc. ("Gyre")) regarding a transaction in which our group will invest the BC shares held by our group in kind to CBIO (now Gyre) and the shares of CBIO (now Gyre) will be received by our group as consideration, and we concluded the business combination agreement on the same date. The transaction was completed on October 31, 2023 under this agreement.

(1) Summary of the Transaction

① Name and business of the acquired company

Name of the acquired company: Catalyst Biosciences, Inc. (now Gyre Therapeutics, Inc.)

Business Activities Research and development of biopharmaceuticals

② Main reasons for the business combination

To date, our Group has promoted a business structure that spans 3 countries: Japan, the United States and China. In the pharmaceuticals business, which is 1 of the pillars of this strategy, we have been building an efficient R&D and manufacturing/sales system in China and promoting a strategy of deploying the results in other regions of the world. Through this transaction, we are able to accelerate clinical-development in the United States through CBIO (currently Gyre).

③ Acquisition date

October 31, 2023

④ Method of acquiring control of the acquired company

Acquisition of shares through investment in kind and conversion of preferred stock into common stock

(2) Consideration for acquisition

Calculation is underway at this time.

(3) Goodwill, assets acquired and liabilities assumed

It has not been determined at this time.

(Assignment of Business)

On September 17, 2023, the Board of Directors of Berkeley Biologics LLC ("BB"), a subsidiary of our consolidated subsidiary Berkeley Advanced Biomaterials Inc., resolved to conclude an agreement with Elutia to acquire the business and concluded an agreement for the transfer of the business on the same date. In addition, the business acquisition was completed on November 9, 2023 pursuant to the agreement.

(NOTE) BB is a newly established corporation for the above-mentioned company acquisition.

(1) Summary of Business Acquisition

- ① The name of the Assignee Company and the content of its business;

Name Elutia Inc. of the transferred company

Business Activities Development and commercialization of orthobiologics products

- ② Reason for acquisition of business

Our Group has been developing its business in Japan, the United States, and China with the 2 pillars of the pharmaceutical business and the medical device (bio-materials) business under the mission of "Becoming a New Desire for Our Patient." In the biomaterials business, BAB, our consolidated subsidiary, has been developing its business mainly in the United States. Recently, we have decided to acquire a part of the orthobiologics business of Elutia in order to further develop this biomaterial business.

- ③ Date of acquisition of business

November 9, 2023

- ④ Legal form of business acquisition

Acquisition of business for cash consideration

(2) Consideration for acquisition

Cash US\$15 million

In addition to the above, a contingent consideration agreement has been reached with Elutia. Over the next 5 years, contingent consideration of up to an additional \$20 million will be paid in cash to Elutia based on the degree of performance result; however, the fair value of the contingent consideration at the date of acquisition of the business has not been determined at this time.

(3) Goodwill, assets acquired and liabilities assumed

It has not been determined at this time.

2 [Others]

Not applicable.

Part II [Information on Guarantee Companies, etc. of Submitting Companies]

Not applicable.

Independent Auditors' Quarterly Review Report

November 14, 2023

GNI Group Ltd.

To the Board of Directors

Taiyo & Co., Ltd.

Tokyo Office

Designated Limited Liability Partners Partners administering the affairs	Certified Public Accountant	Tatsuya Arai
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Designated Limited Liability Partners Partners administering the affairs	Certified Public Accountant	Yoshihiro Imagawa seal
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Auditor's conclusion

In accordance with the provisions of Article 193-2, Paragraph 1 of the Financial Instruments and Exchange Act, the Company shall during the 3Q (July 1, 2023 to September 30, 2023) and the third quarter (January 1, 2023 to September 30, 2023) of GNI Group Ltd. from January 1, 2023 to December 31, 2023 Quarterly reviews of these summarized quarterly consolidated financial statements, namely, the Summary Quarterly Consolidated Statement of Financial Position, the Summary Quarterly Consolidated Statement of Income, the Summary Quarterly Consolidated Statement of Changes in Equity, the Summary Quarterly Consolidated Statement of Cash Flows, and the Notes to the Summary Quarterly Consolidated Financial Statements were conducted.

In our quarterly review, we did not believe in all material respects that the condensed quarterly consolidated financial statements referred to above did not present fairly the financial position of GNI Group Ltd. and its consolidated subsidiaries as of September 30, 2023, the results of their operations for the 3Q and 3Q of the year then ended, and their cash flows for the third quarter of the year in conformity with International Accounting Standards 34, "Interim Financial Reporting" as defined by Article 93 of the Regulations Concerning Terminology, Forms and Preparation Methods of Quarterly Consolidated Financial Statements.

Basis for the auditor's conclusion

We conducted our quarterly review in accordance with the quarterly review standards generally accepted in Japan. Our responsibility under the standards for quarterly reviews is set forth under the caption "Auditor's Responsibility in Quarterly Review of Condensed Quarterly Consolidated Financial Statements." We are independent of the Company and its consolidated subsidiaries in accordance with the provisions of the Code of Professional Ethics in Japan and we fulfill our other ethical responsibilities as an auditor. We believe that the evidence upon which we base our conclusions is obtained.

Responsibility of Management and the Audit Committee for the Condensed Quarterly Consolidated Financial Statements

Management is responsible for the preparation and fair presentation of the condensed quarterly consolidated financial statements in accordance with International Accounting Standards 34, Interim Financial Reporting. This includes the design, implementation, and maintenance of internal control as management deems necessary to enable the preparation and fair presentation of condensed quarterly consolidated financial statements that are free from material misstatement, whether due to fraud or error.

In preparing the condensed quarterly consolidated financial statements, management is responsible for evaluating whether it is appropriate to prepare the condensed quarterly consolidated financial statements based on the going concern assumption and for disclosing matters related to a going concern in accordance with International Accounting Standards No. 1, Presentation of Financial Statements, Item 4.

The responsibility of the Audit Committee is to monitor the execution of the duties of executive officers and directors in the development and operation of the financial reporting process.

Auditor's Responsibility for the Quarterly Review of Condensed Quarterly Consolidated Financial Statements

The auditor's responsibility is to independently express a conclusion on the condensed quarterly consolidated financial statements in the quarterly review report based on the quarterly review performed by the auditor.

In accordance with quarterly review standards generally accepted in Japan, the auditor shall, through the course of the quarterly review, make judgments as an professional expert and conduct the following with professional skepticism:

- Conduct questions, analytical procedures and other quarterly review procedures mainly for management, persons responsible for financial and accounting matters, etc. The quarterly review procedures are limited compared with the procedures for auditing the financial statements for the fiscal year conducted in accordance with auditing standards generally accepted in Japan.
- If the Company determines that there is significant uncertainty with respect to events or circumstances that raise substantial doubt about the Company's ability to continue as a going concern, the Company will conclude, based on the evidence obtained, whether there are any matters in the condensed quarterly consolidated financial statements that would cause the Company to believe that they are not fairly presented in accordance with International Accounting Standards No. 1, Presentation of Financial Statements, Item 4. In addition, if there is material uncertainty regarding the Company's ability to continue as a going concern, the Company is required to alert the notes to the condensed quarterly consolidated financial statements in the quarterly review report or, if the notes to the condensed quarterly consolidated financial statements for material uncertainty are not appropriate, express a limited conclusion or a negative conclusion on the condensed quarterly consolidated financial statements. The auditor's conclusion is based on evidence obtained through the date of the quarterly review report; however, future events and circumstances may prevent the company from continuing as a going concern.
- Evaluate whether the presentation, composition and content of the condensed quarterly consolidated financial statements, including the related notes, as well as whether there are any matters that cause the Company to believe that the presentation and notes to the condensed quarterly consolidated financial statements are not in accordance with International Accounting Standards 34, Interim Financial Reporting, and whether there are any matters that cause the Company to believe that the condensed quarterly consolidated financial statements do not fairly present the underlying transactions and accounting events.
- Obtain evidence regarding the financial information of the Company and its consolidated subsidiaries to express a conclusion on the condensed quarterly consolidated financial statements. The auditor is responsible for directing, supervising and implementing the quarterly review of the condensed quarterly consolidated financial statements. The auditor is solely responsible for the auditor's conclusions.

The auditor reports to the Audit Committee on the scope of the planned quarterly review and the timing of its implementation, as well as significant findings for the quarterly review.

The auditor shall report to the Audit Committee on compliance with the professional ethics provisions of independence in our country and on matters that are reasonably likely to affect the auditor's independence and on the content of safeguards, if any, to eliminate or mitigate impediments.

Interest

There is no interest between the Company and its Consolidated Subsidiaries and the Auditing Corporation or its Operating Partners that should be stated pursuant to the provisions of the Certified Public Accountants Act.

Or more

(NOTE) (1) The above is a computerized version of the original quarterly review report and the original document is maintained separately by us (the company submitting the quarterly report).

2 XBRL data is not included in the scope of quarterly reviews.

[Cover]	
[Filing]	Confirmation letter
[Articles of Basis]	Article 24-4-8(1) of the Financial Instruments and Exchange Act
[Submit to]	Kanto Finance Bureau
[Submission date]	November 14, 2023
[Company Name]	GNI Group Ltd.
[English translation name]	GNI Group Ltd.
[Title of Representative]	Ying Luo, Director, Representative Executive Officer, President and CEO
[Title of Chief Financial Officer]	Toshiya Kitagawa Executive Officer and CFO
[Location of the head office]	2-2, Nihonbashi-Honcho 2-chome, Chuo-ku, Tokyo
[Locations for Public Inspection]	Tokyo Stock Exchange, Inc. (2-1, Nihonbashi Kabutocho, Chuo-ku, Tokyo)

1 [Matters concerning appropriateness of contents of quarterly report]

Ying Luo, Director, Representative Executive Officer, President and CEO, and Toshiya Kitagawa, Executive Officer and CFO, confirmed that the contents of our quarterly report for the 2023rd quarter (from July 1, 2023 to September 30, 2023) were fairly stated in accordance with the Financial Instruments and Exchange Act.

2 [Special Note]

There are no notable items to note when confirming.