Disclaimer: This translation is prepared and provided for readers' convenience only. This summary does not constitute any guarantee, and the Company will not compensate any losses and/or damage stemming from actions taken based on these statements. In the case that there is any discrepancy between the Japanese and English versions, the Japanese version is assumed to be correct.



Summary of Consolidated Financial Results for the Fiscal Year Ended December 31, 2022 (JGAAP)

Listed company's name: RaQualia Pharma Inc.

Listed on: Tokyo Stock Exchange (TSE)

Stock code: 4579

URL: https://www.raqualia.com/

Representative: Hirobumi Takeuchi, President and CEO

Contact: Hidefumi Sugiyama, General Manager, Finance & Accounting Dept. (TEL) +81-52-446-6100

Scheduled date of general meeting of shareholders: March 24, 2023

Scheduled date of dividend payment: -

Scheduled date of filing of securities report: March 27, 2023

Supplementary documents for financial results: Yes Financial results briefing: Yes

(Amounts are rounded down to the nearest million yen.)

1. Consolidated financial results for the fiscal year ended December 31, 2022 (January 1, 2022 to December 31, 2022)

(1) Consolidated operating results

(Percentage figures represent changes from the previous fiscal year.)

| | Net sal | sales Operat | | profit | Ordinary profit | | Profit attributable to owners of parent | |
|-------------------|-------------|--------------|-------------|--------|-----------------|-----|---|-------|
| Fiscal year ended | million yen | % | million yen | % | million yen | % | million yen | % |
| December 31, 2022 | 2,918 | 5.1 | 866 | 22.4 | 904 | 4.7 | 723 | (4.3) |
| December 31, 2021 | 2,776 | 150.7 | 707 | - | 863 | _ | 755 | _ |

Note: Comprehensive income Fiscal year ended December 31, 2022: 693 million yen [(10.5)%] Fiscal year ended December 31, 2021: 774 million yen [-%]

| | Earnings per share (Basic) | Earnings per share (Diluted) | Profit/equity | Ordinary profit/ total assets | Operating profit/ net sales |
|-------------------|----------------------------|------------------------------|---------------|-------------------------------|-----------------------------|
| Fiscal year ended | yen | yen | % | % | % |
| December 31, 2022 | 34.50 | 34.47 | 14.1 | 15.7 | 29.7 |
| December 31, 2021 | 36.07 | 36.04 | 17.2 | 18.2 | 25.5 |

Reference: Share of (profit) loss of entities accounted for using equity method:

Fiscal year ended December 31, 2022: – million yen
Fiscal year ended December 31, 2021: – million yen

(2) Consolidated financial position

| | Total assets | Net assets | Equity ratio | Net assets per share |
|-------------------|--------------|-------------|--------------|----------------------|
| As of | million yen | million yen | % | yen |
| December 31, 2022 | 6,257 | 5,496 | 87.7 | 261.65 |
| December 31, 2021 | 5,234 | 4,788 | 91.3 | 227.97 |

Reference: Equity As of December 31, 2022: 5,488 million yen As of December 31, 2021: 4,777 million yen

(3) Consolidated cash flows

| | Cash flows from operating activities | Cash flows from investing activities | Cash flows from financing activities | Cash and cash equivalents at end of period |
|-------------------|--------------------------------------|--------------------------------------|--------------------------------------|--|
| Fiscal year ended | million yen | million yen | million yen | million yen |
| December 31, 2022 | 1,480 | (47) | (29) | 3,679 |
| December 31, 2021 | 366 | (279) | (16) | 2,240 |

2. Dividends

| | | Annua | dividends po | Total cash | Dividend | Ratio of | | |
|---|-------------------|--------------------|--------------|---------------------|----------|-------------|--------------------------------|--|
| | First quarter-end | Second quarter-end | | Fiscal year- end | Total | dividends | payout ratio (Consolidated) | dividends to net assets (Consolidated) |
| | yen | yen | yen | yen | yen | million yen | % | % |
| Fiscal year ended December 31, 2021 | - | 0.00 | - | 0.00 | 0.00 | - | - | - |
| Fiscal year ended December 31, 2022 | _ | 0.00 | _ | 0.00 | 0.00 | - | - | _ |
| Fiscal year ending December 31, 2023 (forecast) | _ | 0.00 | _ | 0.00 | 0.00 | | _ | |

3. Forecasts of consolidated financial results for the fiscal year ending December 31, 2023 (January 1, 2023 to December 31, 2023)

(Percentage figures represent changes from the previous fiscal year.)

| | Net sale | es | Operating profit | | Ordinary profit | | Profit attributable to owners of parent | | Earnings per share (Basic) |
|--------------------------------------|-------------|-------|------------------|--------|-----------------|--------|---|--------|-------------------------------|
| | million yen | % | million yen | % | million yen | % | million yen | % | yen |
| Fiscal year ending December 31, 2023 | 2,799 | (4.1) | 260 | (69.9) | 242 | (73.2) | 183 | (74.7) | 8.74 |

Note: As the Company conducts performance management on an annualized basis, forecasts of results over a six-month period are not presented.

* Notes

- (1) Changes in significant subsidiaries during the fiscal year ended December 31, 2022 (changes in specified subsidiaries resulting in the change in scope of consolidation): None
- (2) Changes in accounting policies, changes in accounting estimates, and restatements of prior financial statements
 - a. Changes in accounting policies due to the revisions to accounting standards and other regulations: Yes
 - b. Changes in accounting policies due to other reasons: None
 - c. Changes in accounting estimates: None
 - d. Restatements of prior financial statements: None
- (3) Number of issued shares (common shares)
 - a. Total number of issued shares at the end of the period (including treasury shares)

| As of December 31, 2022 | 20,977,181 shares |
|-------------------------|-------------------|
| As of December 31, 2021 | 20,955,142 shares |

b. Total number of treasury shares at the end of the period

| As of December 31, 2022 | 50 shares |
|-------------------------|-----------|
| As of December 31, 2021 | 50 shares |

c. Average number of outstanding shares during the period

| For the fiscal year ended December 31, 2022 | 20,969,376 shares | |
|---|-------------------|--|
| For the fiscal year ended December 31, 2021 | 20,953,020 shares | |

(Reference) Overview of non-consolidated financial results

Non-consolidated financial results for the fiscal year ended December 31, 2022 (January 1, 2022 to December 31, 2022) (1) Non-consolidated operating results

(Percentage figures represent changes from the previous fiscal year.)

| | Net sal | Net sales | | Operating profit | | Ordinary profit | | t |
|-------------------|-------------|-----------|-------------|------------------|-------------|-----------------|-------------|-------|
| Fiscal year ended | million yen | % | million yen | % | million yen | % | million yen | % |
| December 31, 2022 | 2,681 | 13.5 | 683 | 35.1 | 701 | 6.9 | 583 | (5.1) |
| December 31, 2021 | 2,361 | 134.0 | 505 | _ | 656 | = | 614 | _ |

| | Earnings per share (Basic) | Earnings per share (Diluted) |
|-------------------|----------------------------|------------------------------|
| Fiscal year ended | yen | yen |
| December 31, 2022 | 27.83 | 27.81 |
| December 31, 2021 | 29.34 | 29.31 |

(2) Non-consolidated financial position

| | Total assets | Net assets | Equity ratio | Net assets per share |
|-------------------|--------------|-------------|--------------|----------------------|
| As of | million yen | million yen | % | yen |
| December 31, 2022 | 6,091 | 5,346 | 87.6 | 254.49 |
| December 31, 2021 | 5,210 | 4,777 | 91.5 | 227.47 |

Reference: Equity As of December 31, 2022: 5,338 million yen As of December 31, 2021: 4,766 million yen

* Appropriate use of financial forecasts and other special remarks

(Caution concerning forward-looking statements)

Forward-looking statements provided in this document, including financial forecasts, are based on the information currently available to the Company and certain assumptions considered reasonable. Such statements are included without any guarantee as to their future achievement. Actual results, etc. may differ materially from the forecasts depending on various factors.

(Method of accessing supplementary documents for financial results and details of financial results briefing)

The Company plans to hold financial results briefings for institutional investors and analysts on Thursday, February 16, 2023, and for general investors on Friday, February 17, 2023.

The Company plans to post the documents used at the briefings on its website promptly after the briefings are held.

^{*} Financial results reports are exempt from audit conducted by certified public accountants or an audit corporation.

Contents of attachment

| 1. (| Overview of consolidated operating results and others | 2 |
|------|---|----|
| (1) | | |
| (2) | Overview of consolidated financial position for the fiscal year under review | 6 |
| (3) | Overview of cash flows for the fiscal year under review | 6 |
| (4) | Outlook for the fiscal year ending December 31, 2022 | 7 |
| 2. E | Basic rationale for selecting the accounting standard | 7 |
| 3. (| Consolidated financial statements and significant notes thereto | 8 |
| (1) | Consolidated balance sheet | 8 |
| (2) | Consolidated statement of income and consolidated statement of comprehensive income | 10 |
| | Consolidated statement of income | 10 |
| | Consolidated statement of comprehensive income | 11 |
| (3) | Consolidated statement of changes in equity | 12 |
| (4) | Consolidated statement of cash flows | 14 |
| (5) | Notes to consolidated financial statements | 16 |
| | Notes on premise of going concern | 16 |
| | Changes in accounting policies | 16 |
| | Additional information | 16 |
| | Segment information, etc | 17 |
| | Per share information | 18 |
| | Significant subsequent event | 19 |

1. Overview of consolidated operating results and others

(1) Overview of consolidated operating results for the fiscal year under review

(General overview)

During the fiscal year ended December 31, 2022, the Japanese economy experienced a slow recovery in personal consumption in the first half of the year. This was amid a prolonged intensity of impact from COVID-19 and rising prices due to the rapid depreciation of the yen and the turmoil caused by Russia's invasion of Ukraine as personal consumption recovery was delayed. Although corporate capital investment showed steady expansion to support the economy and consumer spending picked up in the second half of the year, accelerated inflation in the U.S. and Europe and declining exports due to the economic downturn slowed recovery.

In the pharmaceutical industry, while many companies achieved strong results from overseas sales, others suffered harm to business conditions due to sluggish domestic sales growth and soaring costs for active pharmaceutical ingredients, raw materials, and clinical development costs overseas. Since the mid-year revision implemented in 2021, annual NHI drug price revisions have become the norm, and there is strong concern that the attractiveness of the pharmaceutical market in Japan will further decline. In addition to the emerging tendency of foreign companies to shy away from the Japanese market, and criticisms of the resurgence of "drug lag," a situation of delayed approval in Japan of new drugs used overseas, there are now frequent mentions of the term "drug loss," referring to a situation where new drugs do not enter Japan. In addition, the issue of short pharmaceutical supplies, triggered by the quality fraud issue of generic manufacturers, has had a significant impact on the medical field and the pharmaceutical market.

Such industry trends as these had no small impact on the business development activities of drug discovery ventures, like the Group, that operate a drug discovery business.

Under such conditions, the Group pursued activities to create development candidate compounds for pharmaceuticals based on internal, independent research or collaborative research with partner companies or academies and to expand its research and development portfolio, while also promoting licensing activities for development candidate compounds it owns and research and development to enhance value.

Accordingly, business activities for the fiscal year under review were as follows.

Regarding human drug products that have been launched, sales of K-CAB® (generic name: tegoprazan)—a drug for gastroesophageal reflux disease marketed by HK inno.N Corporation (headquarters: Osong, South Korea, "HK inno.N")—in South Korea continued to perform well from the previous year, with sales in the fiscal year from external prescriptions of 125.2 billion won, an increase of 14.2% compared with the previous fiscal year, equivalent to approximately 12.5 billion yen at 0.10 yen to the won. Furthermore, HK inno.N received manufacturing and marketing approval in South Korea for the product as a maintenance treatment for patients with cured erosive esophagitis, resulting in five indications for which the product has received manufacturing and marketing approval from the South Korean Ministry of Food and Drug Safety. This makes K-CAB® the drug with the greatest number of indications among all the Potassium Competitive Acid Blocker-based gastric acid secretion inhibitors (P-CABs) sold in South Korea. These developments helped lead to increased sales royalty income for the Company.

Global expansion of tegoprazan is also progressing well. The Company has executed exclusive license agreements with HK inno.N for the development, marketing and manufacturing of tegoprazan with sublicensing rights, and the companies which have entered into the license agreements with HK inno.N (the "sublicensees") are engaged in development, manufacturing and marketing in their respective countries and regions.

In China, sublicensee Shandong Luoxin Pharmaceutical Group Co., Ltd. (headquarters: Shandong Province, China, "Luoxin"), obtained manufacturing and marketing approval and commenced product sales. Similarly, in the Philippines, sublicensee Metro Pharma Phils. Inc. (headquarters: Manila, Philippines, "MPPI"), obtained marketing approval and commenced product sales. In Indonesia, sublicensee PT Kalbe Pharma Tbk (headquarters: Jakarta, Indonesia, "Kalbe") has also received marketing approval. In addition, the product is currently under review or in preparation for submission for approval in a total of 28 countries. Furthermore, in the U.S., sublicensee Braintree Laboratories, Inc. (headquarters: Massachusetts, U.S., "Braintree") has started Phase III clinical trials.

In line with its goal of expanding into 100 countries globally, HK inno.N is searching for sublicensees in other regions. In the fiscal year under review, it concluded a new drug product supply agreement with a local company in Malaysia, as well as a license agreement for seven countries including India with Dr. Reddy's Laboratories Limited (headquarters: Hyderabad, India). As a result of the above progress, the Company received milestone income or a portion of the income earned by HK inno.N from its sublicensees in accordance with the agreement with HK inno.N, in accordance with development progress.

With regard to pet drugs, sales were strong for GALLIPRANT® (generic name: grapiprant), which is a drug for osteoarthritis in dogs, and ENTYCE® (generic name: capromorelin), which has an indication for anorexia management for dogs, and ELURA® (generic name: capromorelin), which has an indication for weight loss management in cats with chronic kidney failure, all of

which were licensed to Elanco Animal Health Inc. (headquarters: Indiana, U.S., "Elanco"). In particular, GALLIPRANT® has become one of Elanco's most profitable products, maintaining double-digit growth in the U.S., the world's largest pet drug market, five years after its launch in 2017. Since medical care for pets is basically at owners' own expenses, there is no drug price system for pet pharmaceuticals, and the industry is characterized by the fact that official drug prices are not cut as in human pharmaceuticals, and manufacturers have strong pricing power for products highly rated by pet owners. These developments also helped lead to increased sales royalty income for the Company in pet pharmaceuticals. With respect to ELURA®, Elanco has filed for approval in Europe, and the Company has received a lump-sum payment of 1 million U.S. dollars for milestone achievement.

Other licensed programs also progressed through the pre-clinical development stage or later at licensee companies.

Eli Lilly and Company (headquarters: Indiana, U.S., "Eli Lilly") has initiated Phase II clinical trials for a P2X7 receptor antagonist (RQ-00466479/AK1780) discovered through collaborative research with Asahi Kasei Pharma Corporation (headquarters: Chiyoda, Tokyo, "Asahi Kasei Pharma") and licensed to Eli Lilly by Asahi Kasei Pharma last year. As a result, the Company received a lump-sum payment of 4 million U.S. dollars from Asahi Kasei Pharma for achievement of this milestone. In addition, Xgene Pharmaceutical Co., Ltd. (headquarters: Hong Kong, "Xgene") has started preclinical studies for the TRPM8 blocker (RQ-00434739) licensed to Xgene last year.

For the cyclooxygenase inhibitor (COX-2 inhibitor, RQ-00317076/AAT-076), which was licensed out to AskAt Inc. (headquarters: Nagoya, Aichi, "AskAt"), AskAt entered into a license agreement with Velo-1, Inc. (headquarters: Tennessee, U.S., "Velo-1") for use as a pet pharmaceutical, and as a result, the Company received a lump-sum payment from AskAt.

As for licensing preparation programs, pre-clinical trials progressed during the fiscal year under review for a ghrelin receptor agonist, which is being developed in-house. In addition, the Company holds the rights to develop, manufacture, and market tegoprazan in Japan, but in order to achieve a speedy launch of the drug in Japan, the Company is preparing for clinical development and are in discussions to secure potential partners. For other licensing preparation programs, the Company conducted business development activities aimed at finding business partners through face-to-face meetings as well as online conferences.

As for programs in the discovery research stage, collaborative research with ASKA Pharmaceutical Co., Ltd. (headquarters: Minato, Tokyo) has made steady progress. In parallel, the Company promoted internal independent research projects to generate development candidate compounds. Furthermore, in the fiscal year under review, the Company promoted partnership with startups and drug discovery ventures with the aim of strengthening its drug discovery research foundations. As part of this, in May 2022, the Company newly initiated exploration for indication potential for intractable and rare diseases for specific compound(s) owned by the Company in collaboration with SOCIUM Inc. (headquarters: Chuo, Tokyo, "SOCIUM"), using SOCIUM's proprietary disease database and AI-driven drug discovery platform. In addition, for the purpose of validating a new modality concept, the Company invested in STAND Therapeutics Co., Ltd. (headquarters: Minato, Tokyo, "STAND") by subscribing to a portion of its issued share acquisition rights and started a collaborative research project to discover new drugs for intractable and rare diseases by utilizing the Company's ion channel drug discovery technology and STAND's intracellular antibody production technology. Similarly, as a modality-related initiative, in December 2022, the Company entered into a collaborative research agreement with Veritas In Silico Inc. (headquarters: Shinagawa, Tokyo), which has platform technology specialized in drug discovery for mRNA, for the creation of small molecule drugs targeting mRNA. Furthermore, in the same month, the Company entered into a collaborative research agreement with D. Western Therapeutics Institute (headquarters: Nagoya, Aichi) for the discovery of therapeutic drugs for ocular diseases.

Clinical trials for the treatment of myelodysplastic syndrome (MDS) and acute myeloid leukemia (AML) are underway in the U.S. for a retinoic acid receptor alpha agonist (tamibarotene, TM-411/SY-1425), licensed by the Company's consolidated subsidiary TMRC Co., Ltd. ("TMRC") to Syros Pharmaceuticals Inc. (headquarters: Massachusetts, U.S., "Syros").

In addition, at a meeting of the Board of Directors held on December 20, 2022, the Company resolved to issue new shares (the "Shares") and the 16th series of share acquisition rights (the "Share Acquisition Rights") by way of third-party allotment and to enter into a purchase agreement for the Shares and Share Acquisition Rights on the same date with CVI Investments, Inc. (headquarters: Cayman Islands, the "Scheduled Allottee").

Based on the business plan and growth potential announced in February 2022, the Company is implementing a mid- to long-term investment strategy to increase and maximize shareholder value, and plans to invest a total of 2,393 million yen in R&D through the fiscal year ending December 31, 2024. Since it is necessary to maintain a high level of R&D investment in order to enhance the development pipeline and accelerate the progress of the development stage, the Company has decided to procure approximately 2,800 million yen, which will be newly required over the next five years, through third-party allotment of the

Shares and Share Acquisition Rights to the allottee. The Scheduled Allottee is a U.S. institutional investor with extensive experience in investing in biotechnology companies and has the capacity for mid- to long-term investments. It is managed by Heights Capital Management, Inc., a member of the Susquehanna International Group, one of the world's largest financial conglomerates, and has over 100 biotechnology investments and assets under management group-wide.

The funds to be procured through the issuance and exercise of the Shares and Share Acquisition Rights will be used for clinical development of existing programs and new compounds, exploratory activities for new modalities and investment related to AI drug discovery, and enhancement of laboratory facilities. The planned amount to be procured is 2,723 million yen (excluding 27 million yen for issuance expenses).

Accordingly, financial results for the fiscal year under review were as follows. Business revenue for the period was 2,918 million yen (up 5.1% year on year), operating profit totaled 866 million yen (up 22.4% year on year), ordinary profit totaled 904 million yen (up 4.7% year on year), and profit attributable to owners of parent was 723 million yen (down 4.3% year on year).

Total business expenses were 2,051 million yen (down 0.8% year on year). In terms of the breakdown of this total, in addition to cost of business revenue of 231 million yen (down 27.8% year on year), research and development expenses were 1,248 million yen (up 10.8% year on year) and other selling, general and administrative expenses came to 571 million yen (down 7.9% year on year).

(Research and development activities)

Research and development expenses of the Group during the fiscal year ended December 31, 2022 were 1,248 million yen. The main components of these activities were as follows:

< RaQualia's research and development and collaborative research>

(A) Clinical development phase

a) Potassium-competitive acid blocker (RQ-00000004, tegoprazan)

The rights to this compound for the target indication of gastroesophageal reflux disease (GERD) and other gastric acid-related diseases have been licensed to HK inno.N for regions other than Japan, while the Company holds the rights in Japan. In the fiscal year under review, the Company consulted with the Pharmaceuticals and Medical Devices Agency (PMDA), the regulatory authority, based on its plan to conduct clinical pharmacology studies for rapid and efficient development and approval by utilizing data from South Korea, and also conducted business development activities to search for potential partner companies, proceeding with discussions toward licensing.

b) 5-HT₄ partial agonist (RQ-00000010)

Regarding this compound for the target indication of gastrointestinal dysmotility including gastroparesis, functional dyspepsia, and chronic constipation, partnering activity is underway as a licensing preparation program post-Phase I clinical trials.

c) 5-HT_{2B} antagonist (RQ-00310941)

This compound for the target indication of irritable bowel syndrome with diarrhea (IBS-D) is also in a licensing preparation program post-Phase I clinical trials.

(B) Preclinical development phase

a) Ghrelin receptor agonist (RQ-00433412)

This compound is under development for the target indication of cancer-related anorexia/cachexia syndrome and constipation resulting from spinal cord injury. Continuing from the previous year, preclinical studies have been conducted during the fiscal year under review through outsourcing.

b) Motilin receptor agonist (RQ-00201894)

This compound is under development for the target indication of gastrointestinal dysmotility including gastroparesis, functional dyspepsia, and post-operative ileus, and is in a licensing preparation program, as the preclinical studies required for Phase I clinical trials have been completed.

c) TRPM8 blocker (RQ-00434739)

Based on the license agreement signed in September 2021, the rights to this compound have been licensed to Xgene for regions other than Japan, while the Company continues to hold the rights in Japan. In the fiscal year under review, the Company provided support to Xgene for the start of pre-clinical studies.

(C) Exploratory research phase

a) Independent research project

In addition to promoting exploratory research aimed at creating development candidate compounds for ion channels and other target molecules where the Company has strengths, the Company has also worked to achieve discontinuous growth by combining new initiatives with the strengthening of its existing drug discovery research base, through

collaborations with the pharmaceutical companies listed below, in order to expand its drug discovery disease areas, expand modalities, and strengthen the drug discovery value chain.

b) Collaborative research with companies

Collaborative research implemented with companies in the fiscal year under review is as follows.

| Company | Start date | Content |
|-----------------------------------|----------------|--|
| ASKA Pharmaceutical Co., Ltd. | July 2019 | Collaborative research with respect to drug discovery research targeting at a specific ion channel |
| Epigeneron, Inc. | September 2019 | Collaborative research for the creation of drugs for treating idiopathic pediatric nephrotic syndrome |
| SOCIUM Inc. | May 2022 | Collaborative research to explore the potential of the Company's compounds for intractable and rare diseases |
| STAND Therapeutics Co., Ltd. | August 2022 | Verification of the feasibility of drug discovery application of intracellular antibody technology (from STAND) for the creation of therapeutic agents for intractable and rare diseases |
| D. Western Therapeutics Institute | December 2022 | Collaborative research for discovery of therapeutic drugs for ocular diseases |
| Veritas In Silico Inc. | December 2022 | Collaborative research for discovery of small-molecule drugs targeting messenger RNA (mRNA) |

c) Collaborative research with academia

Drug discovery research was conducted with Gifu Pharmaceutical University, with whom the Company established a collaborative research chair "Joint Research Chair of Innovative Drug Discovery" in April 2021, mainly for indication of retinal vein occlusion. With regard to the collaborative research with National Research Center for the Control and Prevention of Infectious Diseases Nagasaki University/Department of Emerging Infectious Diseases, Institute of Tropical Medicine, Nagasaki University, which had been underway since September 2020 with the target indication of COVID-19, research aimed at creating a development candidate compound has been terminated and the collaboration has been migrated to academic research. In addition, several other early-stage collaborations aimed at discovering drug targets are underway.

<Status of development at licensee corporation>

a) tegoprazan (K-CAB®, RQ-00000004/LXI-15028, etc.)

In July 2022, HK inno.N received manufacturing and marketing approval from the South Korean Ministry of Food and Drug Safety for maintenance therapy for patients with cured erosive esophagitis, bringing the total number of approved indications in South Korea to five: erosive esophagitis, non-erosive reflux disease, gastric ulcer, adjuvant therapy for Helicobacter pylori eradication, and maintenance treatment for patients with cured erosive esophagitis. In addition, a new dosage form, orally disintegrating tablets, was launched in May 2022.

In China, in April 2022, Luoxin received manufacturing and marketing approval from the local authorities for the treatment of erosive esophagitis and began marketing the product in the same month (Chinese brand name (registered trademark): 泰欣賛® (Taixinxan)). Similarly, in the Philippines, MPPI received marketing approval from the local authorities in May 2022 for four indications, including erosive esophagitis, and began marketing the product in November. In Indonesia, Kalbe received marketing approval from the local authorities in November 2022 for the treatment of non-erosive reflux disease. In addition, the product is under review or in preparation for approval in 28 other countries, including Thailand, Vietnam, Mexico, Singapore, and India.

In the U.S., in October 2022, Braintree initiated Phase III clinical trials in patients with erosive esophagitis and non-erosive reflux disease.

b) EP4 antagonist (GALLIPRANT®, grapiprant)

This compound is currently being sold as a drug for osteoarthritis in dogs by Elanco. Since its launch in the U.S. in January 2017, the compound has been launched in over 20 countries around the world and is also being sold in Japan since October 2020.

c) Ghrelin receptor agonist (ENTYCE®, ELURA®, capromorelin)

Two products containing capromorelin, a ghrelin receptor agonist, as an active ingredient are currently being marketed in the U.S.: ENTYCE® for the treatment of anorexia in dogs and ELURA® for the management of weight loss in cats with chronic kidney disease (CKD). ELURA® is currently under review for approval in Europe.

d) Serotonin 5-HT_{2A} and dopamine D₂ receptor blocker (ziprasidone)

Regarding this compound, which was licensed out as a treatment for schizophrenia, in February 2022, the Company terminated the license agreement with Meiji Seika Pharma Co., Ltd. (headquarters: Chuo, Tokyo), and returned the rights to develop and market ziprasidone in Japan to the licensor.

e) P2X7 receptor antagonist (RQ-00466479/AK1780)

In November 2022, Eli Lilly initiated Phase II clinical trials for this compound, which was created through collaborative research with Asahi Kasei Pharma and licensed to Eli Lilly by Asahi Kasei Pharma, for the treatment of patients with chronic pain.

f) EP4 antagonist (RQ-0000007/AAT-007, grapiprant)

Continuing from the previous year, AskAt's licensee 3D Medicines Inc. (headquarters: Shanghai, China, "3DM") completed Phase I clinical trials in China for the indication of pain, and Ningbo NewBay Medical Technology Development Co., Ltd. (headquarters: Zhejiang, China), another of AskAt's licensees, is conducting Phase I clinical trials in China in the area of oncology.

In the U.S., Ikena Oncology Inc. (headquarters: Massachusetts, U.S.), a sublicensee of AskAt, was conducting Phase I clinical trials for the cancer immunotherapy drug. However, in December 2022, the company announced that it would discontinue its in-house clinical development and consider strategic alternative plans.

g) Cyclooxygenase-2 (COX-2) inhibitor (RQ-00317076/AAT-076)

Continuing from last year, AskAt's licensee 3DM is conducting Phase I clinical trials in China for the indication of pain. In addition, Velo-1 is preparing a pilot study for pet pharmaceutical applications.

h) CB2 agonist (RQ-00202730/AAT-730)

Oxford Cannabinoid Technologies Ltd. (headquarters: London, U.K.), a licensee of AskAt, has completed pre-clinical studies and is preparing to begin clinical trials.

i) TRPM8 blocker (RQ-00434739)

With respect to this compound licensed to Xgene in September 2021, Xgene has started pre-clinical studies for the development for the treatment of chronic pain.

j) Sodium channel blocker (RQ-00350215)

For this compound licensed to Hisamitsu Pharmaceutical Co., Inc. (headquarters: Tosu, Saga, "Hisamitsu Pharmaceutical") in December 2021, Hisamitsu Pharmaceutical is preparing pre-clinical studies for the development of a transdermal chronic pain treatment.

k) Development candidate compound for a specific ion channel target (no compound code disclosed)

Regarding this compound discovered through collaborative research with EA Pharma Co., Ltd. (headquarters: Chuo, Tokyo, "EA Pharma"), EA Pharma continues to develop it.

1) Selective sodium channel blocker (no compound code disclosed)

Regarding this compound licensed to Maruho Co., Ltd. (headquarters: Osaka, Osaka, "Maruho"), Maruho continues to develop it.

m) Retinoic acid receptor alpha agonist (tamibarotene, TM-411/SY-1425)

For this compound licensed by TMRC to Syros, clinical trials are underway in the U.S. for MDS and AML. In the fiscal year under review, data was reported from the Safety Lead-in portion of the Phase II clinical trial (SELECT-AML-1) being conducted by Syros for AML starting in September 2021. Based on the data obtained, Syros announced plans to initiate the randomized part of the SELECT AML-1 trial in the first quarter of 2023.

(2) Overview of consolidated financial position for the fiscal year under review

Assets

Total assets as of December 31, 2022 were 6,257 million yen, an increase of 1,023 million yen (up 19.6%) from the end of the previous fiscal year. This is mainly attributable to an increase in cash and deposits of 1,330 million yen, a decrease in accounts receivable - trade, and contract assets of 603 million yen, an increase in leased assets of 160 million yen, and an increase in investment securities of 100 million yen.

Liabilities

Total liabilities as of December 31, 2022 were 760 million yen, an increase of 314 million yen (up 70.5%) from the end of the previous fiscal year. This is mainly attributable to an increase in lease obligations of 171 million yen and an increase in accounts payable - other of 93 million yen.

Net assets

Total net assets as of December 31, 2022 were 5,496 million yen, an increase of 708 million yen (up 14.8%) from the end of the previous fiscal year. This is mainly attributable to the recording of profit attributable to owners of parent of 723 million yen.

Consequently, the equity ratio was 87.7% (down 3.6 percentage points from the end of the previous fiscal year).

(3) Overview of cash flows for the fiscal year under review

The balance of cash and cash equivalents ("net cash") as of December 31, 2022 amounted to 3,679 million yen, an increase of 1,438 million yen (up 64.2%) from the end of the previous fiscal year.

The respective cash flows in the fiscal year under review and the factors thereof are as follows.

Cash flows from operating activities

Net cash provided by operating activities was 1,480 million yen, an increase of 1,114 million yen (up 304.4% year on year). This is mainly attributable to the recording of profit before income taxes of 851 million yen and depreciation of 147 million yen, and a cash inflow from a decrease in trade receivables of 603 million yen.

Cash flows from investing activities

Net cash used in investing activities was 47 million yen, a decrease of 231 million yen (down 82.9% year on year). This is mainly attributable to purchase of investment securities of 651 million yen, proceeds from sale of investment securities of 315 million yen, and proceeds from redemption of investment securities of 210 million yen.

Cash flows from financing activities

Net cash used in financing activities was 29 million yen, an increase of 13 million yen (up 79.8% year on year). This is mainly attributable to repayments of lease obligations of 45 million yen.

(Reference) Trend in cash flow-related indicators

| (Trefference) frema in each frem females | | | | | |
|--|--------------------------------|--------------------------------|--------------------------------|--------------------------------|--------------------------------|
| | Fiscal year ended December 31, |
| | 2018 | 2019 | 2020 | 2021 | 2022 |
| Equity ratio (%) | 94.9 | 95.3 | 94.1 | 91.3 | 87.7 |
| Market value equity ratio (%) | 541.9 | 580.9 | 492.8 | 470.0 | 413.0 |
| Interest-bearing debt to cash flow ratio (years) | _ | _ | - | 0.1 | 0.2 |
| Interest coverage ratio (factor) | _ | - | = | 252 | 247 |

Equity ratio: equity / total assets

Market value equity ratio: market capitalization / total assets

Interest-bearing debt to cash flow ratio: interest-bearing debt / cash flow

Interest coverage ratio: cash flow / paid interest

Note 1. Interest-bearing debt to cash flow ratio and interest coverage ratio from the fiscal year ended December 31, 2018 to the fiscal year ended December 31, 2020 are not provided since operating cash flow was a minus figure.

(4) Outlook for the fiscal year ending December 31, 2022

For the next fiscal year (the fiscal year ending December 31, 2023), the Company expects to receive steady royalty income from tegoprazan—a gastro-esophageal reflux disease treatment, GALLIPRANT®—a drug for osteoarthritis in dogs, ENTYCE®—a treatment for anorexia in dogs, and ELURA®—a drug for weight loss management in cats. The Company also expects to earn upfront payments associated with concluding new licensing agreements and milestone income associated with development progress.

In research and development activities, the Company will strive to enhance corporate value by making progress in researchand development-stage projects and by strengthening its drug discovery research infrastructure through collaboration with start-ups, drug discovery ventures, academia, and other partners.

As for the outlook of consolidated financial results for the fiscal year ending December 31, 2023, the Group forecasts business revenue of 2,799 million yen, operating profit of 260 million yen, ordinary profit of 242 million yen and profit attributable to owners of parent of 183 million yen.

The forecast figures presented above are based on the information currently available to the Group and certain assumptions considered reasonable. Such statements are included without any guarantee as to their future achievement. Actual results, etc., may differ materially from the forecasts depending on various factors. In the case where the Group acknowledges the need to revise the financial forecasts, it will disclose such information promptly.

2. Basic rationale for selecting the accounting standard

The Group has adopted Japanese accounting standards to ease the cost, etc., of parallel disclosure of reporting under both Japanese accounting standards and international financial reporting standards (IFRS).

The Group does not have plans to adopt IFRS as of the end of the fiscal year under review; however, its policy is to respond appropriately to the situation in Japan and overseas with regard to adoption trends by other companies in the industry.

3. Consolidated financial statements and significant notes thereto

(1) Consolidated balance sheet

| | As of December 31, 2021 | As of December 31, 2022 |
|--|-------------------------|-------------------------|
| Assets | | |
| Current assets | | |
| Cash and deposits | 2,345,306 | 3,675,450 |
| Accounts receivable - trade | 1,205,401 | _ |
| Accounts receivable - trade, and contract assets | - | 602,311 |
| Securities | 313,807 | 250,599 |
| Work in process | _ | 978 |
| Supplies | 10,547 | 7,522 |
| Advance payments to suppliers | 15,939 | 89,820 |
| Prepaid expenses | 90,382 | 108,633 |
| Other | 22,390 | 86,777 |
| Total current assets | 4,003,775 | 4,822,094 |
| Non-current assets | | |
| Property, plant and equipment | | |
| Buildings | 154,158 | 154,158 |
| Tools, furniture and fixtures | 944,383 | 963,622 |
| Leased assets | 59,772 | 254,926 |
| Accumulated depreciation | (858,924) | (981,683) |
| Total property, plant and equipment | 299,389 | 391,024 |
| Intangible assets | | |
| Trademark right | 3,839 | 4,268 |
| Software | 29,227 | 19,984 |
| Other | 731 | 72 |
| Total intangible assets | 33,799 | 24,325 |
| Investments and other assets | | |
| Investment securities | 887,932 | 987,962 |
| Long-term prepaid expenses | 140 | 24,073 |
| Other | 9,160 | 8,172 |
| Total investments and other assets | 897,233 | 1,020,208 |
| Total non-current assets | 1,230,422 | 1,435,559 |
| Total assets | 5,234,197 | 6,257,653 |

| | | (Thousands of yel |
|---|-------------------------|-------------------------|
| | As of December 31, 2021 | As of December 31, 2022 |
| Liabilities | | |
| Current liabilities | | |
| Accounts payable - trade | 45,996 | 128,066 |
| Current portion of long-term borrowings | _ | 2,620 |
| Lease liabilities | 21,547 | 42,887 |
| Accounts payable - other | 112,768 | 206,209 |
| Accrued expenses | 63,004 | 60,479 |
| Income taxes payable | 80,405 | 30,957 |
| Accrued consumption taxes | 37,475 | _ |
| Deposits received | 28,884 | 18,922 |
| Other | 10,442 | 3,635 |
| Total current liabilities | 400,524 | 493,778 |
| Non-current liabilities | | |
| Long-term borrowings | _ | 9,170 |
| Lease liabilities | 17,520 | 167,661 |
| Asset retirement obligations | 12,129 | 12,222 |
| Provision for share awards | _ | 60,590 |
| Provision for share awards for directors (and other | | 14,498 |
| officers) | _ | 14,496 |
| Deferred tax liabilities | 16,018 | 2,750 |
| Total non-current liabilities | 45,668 | 266,893 |
| Total liabilities | 446,193 | 760,671 |
| Net assets | | |
| Shareholders' equity | | |
| Share capital | 2,256,920 | 2,265,697 |
| Capital surplus | 2,446,703 | 2,455,480 |
| Retained earnings | 49,631 | 773,021 |
| Treasury shares | (21) | (21) |
| Total shareholders' equity | 4,753,234 | 5,494,178 |
| Accumulated other comprehensive income | | |
| Valuation difference on available-for-sale securities | 23,919 | (5,569) |
| Total accumulated other comprehensive income | 23,919 | (5,569) |
| Share acquisition rights | 10,850 | 8,372 |
| Total net assets | 4,788,004 | 5,496,981 |
| Total liabilities and net assets | 5,234,197 | 6,257,653 |
| Total liabilities and net assets | 5,234,197 | 6,257,653 |

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

| | Fiscal year ended December 31, 2021 | Fiscal year ended December 31, 2022 |
|--|--|--|
| Business revenue | 2,776,233 | 2,918,038 |
| Business expenses | | |
| Cost of business revenue | 320,674 | 231,586 |
| Research and development expenses | 1,127,397 | 1,248,678 |
| Other selling, general and administrative expenses | 620,301 | 571,538 |
| Total business expenses | 2,068,373 | 2,051,803 |
| Operating profit | 707,860 | 866,235 |
| Non-operating income | | |
| Interest income | 1,775 | 529 |
| Interest on securities | 21,074 | 13,127 |
| Foreign exchange gains | 145,688 | 43,697 |
| Gain on valuation of derivatives | _ | 13,672 |
| Gain on valuation of compound financial instruments | 50 | _ |
| Subsidy income | 5,785 | |
| Other | 2,967 | 5,622 |
| Total non-operating income | 177,340 | 76,649 |
| Non-operating expenses | | |
| Interest expenses | 1,454 | 5,995 |
| Commitment fees | _ | 5,833 |
| Share issuance costs | 120 | 15,897 |
| Loss on valuation of derivatives | 10,079 | _ |
| Loss on valuation of compound financial instruments | _ | 10,820 |
| Settlement payments | 9,600 | _ |
| Total non-operating expenses | 21,254 | 38,545 |
| Ordinary profit | 863,946 | 904,338 |
| Extraordinary income | | |
| Gain on sale of investment securities | 14,364 | 10,268 |
| Gain on redemption of investment securities | 2,267 | 4,203 |
| Total extraordinary income | 16,632 | 14,472 |
| Extraordinary losses | | |
| Loss on valuation of investment securities | = | 49,999 |
| Retirement benefits for directors (and other officers) | _ | 17,800 |
| Total extraordinary losses | _ | 67,799 |
| Profit before income taxes | 880,579 | 851,011 |
| Income taxes - current | 122,047 | 129,034 |
| Income taxes - deferred | 2,742 | (1,413) |
| Total income taxes | 124,790 | 127,620 |
| Profit | 755,788 | 723,390 |
| Profit attributable to non-controlling interests | | , 25,570 |
| Profit attributable to owners of parent | 755,788 | 723,390 |
| Tions authorizable to owners of parent | 133,100 | 123,390 |

Consolidated statement of comprehensive income

| | | (Thousands of yen) |
|--|--|--|
| | Fiscal year ended December 31, 2021 | Fiscal year ended December 31, 2022 |
| Profit | 755,788 | 723,390 |
| Other comprehensive income | | |
| Valuation difference on available-for-sale securities | 19,110 | (29,489) |
| Total other comprehensive income | 19,110 | (29,489) |
| Comprehensive income | 774,899 | 693,901 |
| Comprehensive income attributable to | | |
| Comprehensive income attributable to owners of parent | 774,899 | 693,901 |
| Comprehensive income attributable to non-controlling interests | _ | _ |

(3) Consolidated statement of changes in equity Fiscal year ended December 31, 2021

| | | Shareholders' equity | | | |
|--|---------------|----------------------|-------------------|-----------------|----------------------------|
| | Share capital | Capital surplus | Retained earnings | Treasury shares | Total shareholders' equity |
| Balance at beginning of period | 2,255,401 | 2,445,184 | (706,157) | (21) | 3,994,407 |
| Changes during period | | | | | |
| Issuance of new shares | 1,519 | 1,519 | | | 3,038 |
| Profit attributable to owners of parent | | | 755,788 | | 755,788 |
| Net changes in items other than shareholders' equity | | | | | - |
| Total changes during period | 1,519 | 1,519 | 755,788 | _ | 758,827 |
| Balance at end of period | 2,256,920 | 2,446,703 | 49,631 | (21) | 4,753,234 |

| | Accumulated other co | omprehensive income | | | |
|--|---|--|--------------------------|------------------|--|
| | Valuation difference on available-for-sale securities | Total accumulated other comprehensive income | Share acquisition rights | Total net assets | |
| Balance at beginning of period | 4,809 | 4,809 | 11,912 | 4,011,129 | |
| Changes during period | | | | | |
| Issuance of new shares | | _ | | 3,038 | |
| Profit attributable to owners of parent | | _ | | 755,788 | |
| Net changes in items other than shareholders' equity | 19,110 | 19,110 | (1,062) | 18,048 | |
| Total changes during period | 19,110 | 19,110 | (1,062) | 776,875 | |
| Balance at end of period | 23,919 | 23,919 | 10,850 | 4,788,004 | |

| | Shareholders' equity | | | | |
|--|----------------------|-----------------|-------------------|-----------------|----------------------------|
| | Share capital | Capital surplus | Retained earnings | Treasury shares | Total shareholders' equity |
| Balance at beginning of period | 2,256,920 | 2,446,703 | 49,631 | (21) | 4,753,234 |
| Changes during period | | | | | |
| Issuance of new shares | 8,776 | 8,776 | | | 17,553 |
| Profit attributable to owners of parent | | | 723,390 | | 723,390 |
| Net changes in items other than shareholders' equity | | | | | _ |
| Total changes during period | 8,776 | 8,776 | 723,390 | - | 740,944 |
| Balance at end of period | 2,265,697 | 2,455,480 | 773,021 | (21) | 5,494,178 |

| | Accumulated other co | omprehensive income | | | |
|--|---|--|--------------------------|------------------|--|
| | Valuation difference on available-for-sale securities | Total accumulated other comprehensive income | Share acquisition rights | Total net assets | |
| Balance at beginning of period | 23,919 | 23,919 | 10,850 | 4,788,004 | |
| Changes during period | | | | | |
| Issuance of new shares | | - | | 17,553 | |
| Profit attributable to owners of parent | | _ | | 723,390 | |
| Net changes in items other than shareholders' equity | (29,489) | (29,489) | (2,477) | (31,966) | |
| Total changes during period | (29,489) | (29,489) | (2,477) | 708,977 | |
| Balance at end of period | (5,569) | (5,569) | 8,372 | 5,496,981 | |

| | Fiscal year ended December 31, 2021 | Fiscal year ended December 31, 2022 |
|--|--|--|
| ash flows from operating activities | | |
| Profit before income taxes | 880,579 | 851,011 |
| Depreciation | 141,555 | 147,731 |
| Interest income | (1,775) | (529) |
| Interest income on securities | (21,074) | (13,127) |
| Interest expenses | 1,454 | 5,995 |
| Commitment fees | _ | 5,833 |
| Foreign exchange losses (gains) | (113,901) | (30,934 |
| Loss (gain) on sale of investment securities | (14,364) | (10,268 |
| Loss (gain) on redemption of investment securities | (2,267) | (4,203 |
| Loss (gain) on valuation of investment securities | _ | 49,999 |
| Loss (gain) on valuation of derivatives | 10,079 | (13,672 |
| Loss (gain) on valuation of compound financial | (50) | 10.000 |
| instruments | (50) | 10,820 |
| Share issuance costs | 120 | 15,897 |
| Subsidy income | (5,785) | |
| Settlement payments | 9,600 | _ |
| Retirement benefits for directors (and other officers) | 2,000 | 17,800 |
| Decrease (increase) in trade receivables | (674,582) | 603,089 |
| Decrease (increase) in inventories | (4,007) | 2,047 |
| Increase (decrease) in trade payables | | 82,070 |
| Decrease (increase) in advance payments to suppliers | 4,166 20,472 | |
| | | (73,881 |
| Decrease (increase) in prepaid expenses | (40,139) | (6,524 |
| Decrease (increase) in accounts receivable - other | 12,737 | 178 |
| Decrease (increase) in consumption taxes refund receivable | 63,146 | (24,032 |
| Increase (decrease) in accrued consumption taxes | 37,475 | (37,475 |
| Increase (decrease) in accounts payable - other | 68,223 | 75,933 |
| Increase (decrease) in accrued expenses | 13,135 | (2,524 |
| Increase (decrease) in income taxes payable - factor based tax | 14,023 | (6,788 |
| Increase (decrease) in deposits received | 25,750 | (9,961 |
| Increase (decrease) in provision for share awards | | 60,590 |
| Increase (decrease) in provision for share awards for | | 14,498 |
| directors (and other officers) | _ | 14,470 |
| Other, net | 972 | (33,274 |
| Subtotal | 425,543 | 1,676,296 |
| Interest and dividends received | 22,460 | 18,128 |
| Interest paid | (1,454) | (6,018 |
| Commitment fees paid | | (7,000 |
| Income taxes paid | (76,707) | (183,521 |
| Subsidies received | 5,785 | _ |
| Payments of retirement benefits for directors (and other officers) | , - | (17,800 |
| Settlement paid | (9,600) | |
| Net cash provided by (used in) operating activities | 366,027 | 1,480,084 |

| | (Thousands of yen |
|--|--|
| Fiscal year ended December 31, 2021 | Fiscal year ended December 31, 2022 |
| | |
| (317,510) | (200,000) |
| 207,380 | 310,130 |
| (200,000) | (100,000) |
| _ | 100,000 |
| (91,494) | (31,132) |
| (13,924) | (773) |
| (200,649) | (651,634) |
| 221,383 | 315,249 |
| 115,065 | 210,512 |
| 497 | _ |
| (279,251) | (47,649) |
| | |
| 10,000 | - |
| (10,000) | _ |
| _ | 13,100 |
| - | (1,310) |
| 1,855 | 4,033 |
| (18,297) | (45,387) |
| (16,441) | (29,563) |
| 109,010 | 35,771 |
| 179,344 | 1,438,643 |
| 2,061,316 | 2,240,661 |
| 2,240,661 | 3,679,304 |
| | (317,510) 207,380 (200,000) (91,494) (13,924) (200,649) 221,383 115,065 497 (279,251) 10,000 (10,000) 1,855 (18,297) (16,441) 109,010 179,344 |

(5) Notes to consolidated financial statements

Notes on premise of going concern

No items to report.

Changes in accounting policies

(Application of accounting standard for revenue recognition, etc.)

The Company has applied the "Accounting Standard for Revenue Recognition" (ASBJ Statement No. 29, March 31, 2020) and relevant ASBJ regulations from the beginning of the fiscal year ended December 31, 2022, and it has recognized revenue at the time the control of promised goods or services is transferred to the customer at the amount expected to be received upon exchange of said goods or services.

The Group earns revenues (upfront payments, milestone-related revenues, royalty income, etc.) from licensing agreements that allow third parties to research, develop, manufacture and sell pharmaceuticals and other products and to use their technologies.

With regard to upfront payments and milestone-related revenues, when performance obligations are satisfied at a point in time, contractual performance obligations are deemed to be satisfied at the time when development, marketing, and other rights are granted, or at the time when the contractually stipulated milestone is achieved. These revenues are recognized as business revenue at the point when contractual performance obligations are deemed to be satisfied.

Royalty income is consideration based on license agreements, etc., calculated based on the sales revenue of the contract partner, etc. This income is recognized as business revenue with consideration to the point in time at which it is incurred.

The application of the Accounting Standard for Revenue Recognition and its guidance is subject to the transitional treatment provided in the proviso to paragraph 84 of the Accounting Standard for Revenue Recognition. The cumulative effect of the retrospective application assuming the new accounting policy had been applied to periods prior to the start of the fiscal year ended December 31, 2022, was added to or subtracted from the opening balance of retained earnings of the fiscal year ended December 31, 2022, and thus the new accounting policy is applied from such opening balance; provided, however, that the new accounting policy is not retrospectively applied to contracts where recognitions of nearly all the revenue amounts for periods prior to the start of the fiscal year ended December 31, 2022, are subject to the previous treatment by applying the method provided for in paragraph 86 of the Accounting Standard for Revenue Recognition. Furthermore, by applying the method set forth in item (1) of the supplementary provisions of paragraph 86 of the Accounting Standard for Revenue Recognition, modifications to contracts carried out prior to the beginning of the fiscal year ended December 31, 2022 were accounted for based on the contractual terms after all contract modifications were reflected. Consequently, this cumulative effect was added to or deducted from the opening balance of retained earnings of the fiscal year ended December 31, 2022.

As a result, there was no effect on the consolidated financial statements for the fiscal year ended December 31, 2022. In addition, there was no effect on the opening balance of retained earnings.

In accordance with the transitional treatment provided for in paragraph 89-2 of the Accounting Standard for Revenue Recognition, figures for the previous fiscal year have not been restated in accordance with the new approach to presentation.

(Application of accounting standard for fair value measurement, etc.)

The Company has applied the "Accounting Standard for Fair Value Measurement" (ASBJ Statement No. 30, July 4, 2019) and relevant ASBJ regulations from the beginning of the fiscal year ended December 31, 2022, and it has applied the new accounting policy provided for by the Accounting Standard for Fair Value Measurement, etc. prospectively in accordance with the transitional measures provided for in paragraph 19 of the Accounting Standard For Fair Value Measurement, and paragraph 44-2 of the "Accounting Standard for Financial Instruments" (ASBJ Statement No. 10, July 4, 2019).

Note that there was no effect on the consolidated financial statements.

Additional information

(Application of tax effect accounting for transition from consolidated taxation system to group tax sharing system)

As for items regarding the transition to the group tax sharing system introduced in the "Act Partially Amending the Income Tax Act" (Act No. 8 of 2020) and items revised on non-consolidated taxation system in connection with the transition to the group tax sharing system, the Company and its consolidated subsidiaries have not applied the provisions of paragraph 44 of the "Guidance on Accounting Standard for Tax Effect Accounting" (ASBJ Guidance No. 28, February 16, 2018) as allowed by the provisions of paragraph 3 of the "Tax Effect Accounting for the Transition from the Consolidated Taxation System to the Group Tax Sharing System" (ASBJ PITF No. 39, March 31, 2020). Accordingly, amounts of deferred tax assets and deferred tax liabilities are determined in accordance with the provisions of the tax law before revision.

(Accounting estimates amid the spread of COVID-19)

The Group has determined the accounting estimates for impairment accounting of non-current assets, etc. based on information available when preparing the consolidated financial statements. The effects of the spread of COVID-19 on the Group are limited at the present time and the Group has determined that there will not be a significant impact on the estimates for the fiscal year under review.

Segment information, etc.

[Segment information]
I. Fiscal year ended I Fiscal year ended December 31, 2021

This information is omitted because the Group consists of a single business segment dealing with research and development of pharmaceutical and related businesses.

II. Fiscal year ended December 31, 2022
This information is omitted because the Group consists of a single business segment dealing with research and development of pharmaceutical and related businesses.

Per share information

| | Fiscal year ended December 31, 2021 | Fiscal year ended December 31, 2022 |
|----------------------------|--|--|
| Net assets per share (Yen) | 227.97 | 261.65 |
| Basic earnings per share | 36.07 | 34.50 |
| Diluted earnings per share | 36.04 | 34.47 |

Notes: 1. The basis for calculation of net assets per share is as follows:

| | As of December 31, 2021 | As of December 31, 2022 |
|---|-------------------------|-------------------------|
| Total net assets (Thousands of yen) | 4,788,004 | 5,496,981 |
| Amount to be deducted from total net assets (Thousands of yen) | 10,850 | 8,372 |
| [Share acquisition rights included therein (Shares)] (Thousands of yen) | [10,850] | [8,372] |
| Amount of net assets at the end of period related to common shares (Thousands of yen) | 4,777,154 | 5,488,609 |
| Number of common shares at the end of period used in calculation of net assets per share (Shares) | 20,955,092 | 20,977,131 |

2. The basis for calculation of basic earnings per share and diluted earnings per share is as follows:

| | Fiscal year ended December 31, 2021 | Fiscal year ended December 31, 2022 |
|---|--|--|
| Basic earnings per share | | |
| Amount of profit attributable to owners of parent (Thousands of yen) | 755,788 | 723,390 |
| Amount not attributable to common shareholders (Thousands of yen) | _ | _ |
| Amount of profit attributable to owners of parent related to common shares (Thousands of yen) | 755,788 | 723,390 |
| Average number of outstanding common shares during the period (Shares) | 20,953,020 | 20,969,376 |
| | | |
| Diluted earnings per share | | |
| Adjustment on profit attributable to owners of parent (Thousands of yen) | - | - |
| Increase in number of common shares (Shares) | 19,084 | 13,764 |
| [Share acquisition rights included therein (Shares)] | - | _ |
| Summary of potential shares that are not included in calculation of diluted earnings per share due to a lack of dilution effect | | |

Significant subsequent event

(Issuance of new shares and the 16th series of share acquisition rights through third-party allotment)

At a meeting of the Board of Directors on December 20, 2022, the Company resolved to issue new shares (the "Shares") and the 16th series of stock acquisition rights (the "Share Acquisition Rights") through third-party allotment, and the payment procedure was completed on January 5, 2023.

The funds to be procured through the issuance and exercise of the Shares and Share Acquisition Rights will be used for clinical development of existing programs and new compounds, exploratory activities for new modalities, investment related to AI drug discovery, and enhancement of laboratory facilities. The planned amount to be procured is 2,723 million yen (excluding 27 million yen for issuance expenses).

A summary of the Shares and Share Acquisition Rights issued is as follows:

1. Overview of the Share Issuance

| (1) | Payment date | January 5, 2023 |
|-----|---|---------------------------------|
| (2) | Number of new shares issued | 625,000 shares of common shares |
| (3) | Issue price | 1,258 yen per share |
| (4) | Amount of procured funds | 786,250,000 yen |
| (5) | Amount of capital to be increased | 393,125,000 yen |
| (6) | Amount of legal capital surplus to be increased | 393,125,000 yen |
| (7) | Method of offering or allotment | Third-party allotment |
| (8) | Allottee | CVI Investments, Inc. |

2. Overview of the Share Acquisition Right Issuance

| (1) Allotment date | Ĭ | |
|--|--|--|
| () | January 5, 2023 | |
| (2) Number of new share acquisition rights issued | 12,500 | |
| (3) Issue price | Total: 19,362,500 yen (per share acquisition right: 1,549 yen) | |
| (4) Number of potential shares due to the issuance | Potential shares: 1,250,000 (100 shares per share acquisition right) The exercise price will not be revised. | |
| (5) Amount of procured funds (value of assets to be contributed upon exercise of share acquisition rights) | 1,945,000,000 yen (Note) | |
| (6) Exercise price and conditions for revision of exercise price | Exercise price: 1,556 yen; the exercise price will not be revised. | |
| (7) Exercise period | From January 6, 2023 to January 5, 2028 | |
| (8) Method of offering or allotment | Third-party allotment | |
| (9) Allottee | CVI Investments, Inc. | |
| (10) Other | The purchase agreement for the Share Acquisition Rights (the "Purchase Agreement") provides for the following: (1) The issuance of the Share Acquisition Rights shall be subject to the fulfillment of the following conditions, etc.: (i) That the Company's representations and warranties set forth in the Purchase Agreement are accurate in all material respects and that the Company has complied with its material covenants (ii) No injunction order, etc. has been issued with respect to the issuance of the Share Acquisition Rights (iii) The Company's shares have not been delisted (iv) No material adverse event has occurred with respect to the Company (v) The Company has not communicated to the Allottee any undisclosed material facts concerning the Company (vi) The securities registration statement filed under the Financial Instruments and Exchange Act with respect to the Share Acquisition Rights is in effect (2) Any transfer of the Share Acquisition Rights shall require the approval of the Company's Board of Directors (however, from the perspective of reducing administrative costs at the Allottee, transfers to Bank of America, J.P. Morgan, Goldman Sachs & Co. and their affiliates shall be excluded). Even in the event of a transfer, the rights and obligations of the Allottee will be taken over by the recipient. In addition, the Purchase Agreement stipulates provisions pertaining to the purchase of the Share Acquisition Rights and provisions pertaining to lock-ups regarding the issuance of new shares, etc. | |

Note: The amount of procured funds will be reduced if the Share Acquisition Rights are not exercised within the exercise period or if the Share Acquisition Rights acquired by the Company are canceled.