

Translation

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February 9, 2024

Consolidated Financial Results for the Fiscal Year Ended December 31, 2023 (Based on Japanese GAAP)

Company name: D.Western Therapeutics Institute, Inc.
Listing: Tokyo
Securities code: 4576
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Scheduled date of ordinary general meeting of shareholders: March 27, 2024
Scheduled date to commence dividend payments: –
Scheduled date to file securities report: March 27, 2024
Preparation of supplementary material on financial results: Yes
Holding of financial results meeting: Yes (for analysts and institutional investors)

(Yen amounts are rounded down to millions, unless otherwise noted.)

1. Consolidated financial results for the fiscal year ended December 31, 2023 (from January 1, 2023 to December 31, 2023)

(1) Consolidated operating results

(Percentages indicate year-on-year changes.)

| Fiscal year ended | Net sales | | Operating profit | | Ordinary profit | | Profit attributable to owners of parent | |
|-------------------|-----------------|-------|------------------|---|-----------------|---|---|---|
| | Millions of yen | % | Millions of yen | % | Millions of yen | % | Millions of yen | % |
| December 31, 2023 | 428 | (4.4) | (798) | – | (796) | – | (812) | – |
| December 31, 2022 | 448 | 8.1 | (305) | – | (295) | – | (429) | – |

Note: Comprehensive income For the fiscal year ended December 31, 2023 ¥(828) million [–%]
For the fiscal year ended December 31, 2022 ¥(442) million [–%]

| Fiscal year ended | Earnings per share | Diluted earnings per share | Profit attributable to owners of parent/equity | Ordinary profit/total assets | Operating profit/net sales |
|-------------------|--------------------|----------------------------|--|------------------------------|----------------------------|
| | Yen | Yen | % | % | % |
| December 31, 2023 | (25.56) | – | (51.8) | (29.9) | (186.4) |
| December 31, 2022 | (14.50) | – | (22.3) | (10.9) | (68.3) |

Reference: Share of profit (loss) of entities accounted for using equity method
For the fiscal year ended December 31, 2023 ¥– million
For the fiscal year ended December 31, 2022 ¥– million

(2) Consolidated financial position

| | Total assets | Net assets | Equity ratio | Net assets per share |
|-------------------|-----------------|-----------------|--------------|----------------------|
| As of | Millions of yen | Millions of yen | % | Yen |
| December 31, 2023 | 2,373 | 1,279 | 53.9 | 39.81 |
| December 31, 2022 | 2,956 | 1,873 | 62.8 | 60.14 |

Reference: Equity

As of December 31, 2023 ¥1,279 million
As of December 31, 2022 ¥1,856 million

(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 | Millions of yen | Millions of yen | Millions of yen | Millions of yen |
| December 31, 2023 | (586) | (15) | 134 | 1,867 |
| December 31, 2022 | (354) | (139) | 867 | 2,334 |

2. Cash dividends

| | Annual dividends per share | | | | | Total cash dividends (Total) | Dividend payout ratio (Consolidated) | Ratio of dividends to net assets (Consolidated) |
|---|----------------------------|-----------------|-----------------|-----------------|-------------|------------------------------|--------------------------------------|---|
| | 1st quarter-end | 2nd quarter-end | 3rd quarter-end | Fiscal year-end | Total | | | |
| Fiscal year ended December 31, 2022 | Yen – | Yen 0.00 | Yen – | Yen 0.00 | Yen 0.00 | Millions of yen – | % – | % – |
| Fiscal year ended December 31, 2023 | – | 0.00 | – | 0.00 | 0.00 | – | – | – |
| Fiscal year ending December 31, 2024 (Forecast) | – | 0.00 | – | 0.00 | 0.00 | | – | |

3. Forecast of consolidated financial results for the fiscal year ending December 31, 2024 (from January 1, 2024 to December 31, 2024)

(Percentages indicate year-on-year changes.)

| | Net sales | | Operating profit | | Ordinary profit | | Profit attributable to owners of parent | | Earnings per share |
|-----------|-----------------|-------|------------------|---|-----------------|---|---|---|--------------------|
| | Millions of yen | % | Millions of yen | % | Millions of yen | % | Millions of yen | % | Yen |
| Full year | 400 | (6.6) | (1,500) | – | (1,510) | – | (1,510) | – | (47.00) |

*** Notes**

- (1) Changes in significant subsidiaries during the fiscal year ended December 31, 2023
(changes in specified subsidiaries resulting in the change in scope of consolidation): No
- (2) Changes in accounting policies, changes in accounting estimates, and restatement of prior period financial statements
- (i) Changes in accounting policies due to revisions to accounting standards and other regulations: No
- (ii) Changes in accounting policies due to other reasons: No
- (iii) Changes in accounting estimates: No
- (iv) Restatement of prior period financial statements: No
- (3) Number of issued shares (common shares)

- (i) Total number of issued shares at the end of the period (including treasury shares)

| | |
|-------------------------|-------------------|
| As of December 31, 2023 | 32,128,012 shares |
| As of December 31, 2022 | 30,871,138 shares |

- (ii) Number of treasury shares at the end of the period

| | |
|-------------------------|------------|
| As of December 31, 2023 | 286 shares |
| As of December 31, 2022 | 100 shares |

- (iii) Average number of shares during the period

| | |
|-------------------------------------|-------------------|
| Fiscal year ended December 31, 2023 | 31,780,063 shares |
| Fiscal year ended December 31, 2022 | 29,639,914 shares |

(Reference) Summary of non-consolidated financial results

1. Non-consolidated financial results for the fiscal year ended December 31, 2023 (from January 1, 2023 to December 31, 2023)

(1) Non-consolidated operating results

(Percentages indicate year-on-year changes.)

| Fiscal year ended | Net sales | | Operating profit | | Ordinary profit | | Profit | |
|-------------------|-----------------|-------|------------------|---|-----------------|---|-----------------|---|
| | Millions of yen | % | Millions of yen | % | Millions of yen | % | Millions of yen | % |
| December 31, 2023 | 427 | 4.0 | (735) | – | (728) | – | (853) | – |
| December 31, 2022 | 411 | (0.1) | (255) | – | (241) | – | (386) | – |

| Fiscal year ended | Earnings per share | Diluted earnings per share |
|-------------------|--------------------|----------------------------|
| | Yen | Yen |
| December 31, 2023 | (26.85) | – |
| December 31, 2022 | (13.05) | – |

(2) Non-Consolidated financial position

| As of | Total assets | Net assets | Equity ratio | Net assets per share |
|-------------------|-----------------|-----------------|--------------|----------------------|
| | Millions of yen | Millions of yen | % | Yen |
| December 31, 2023 | 2,371 | 1,281 | 54.0 | 39.88 |
| December 31, 2022 | 2,973 | 1,900 | 63.9 | 61.53 |

Reference: Equity

As of December 31, 2023 ¥1,281 million
As of December 31, 2022 ¥1,899 million

**2. Forecast of non-consolidated financial results for the fiscal year ending December 31, 2024
(from January 1, 2024 to December 31, 2024)**

(Percentages indicate year-on-year changes.)

| | Net sales | | Ordinary profit | | Profit | | Earnings per share |
|-----------|-----------------|-------|-----------------|---|-----------------|---|--------------------|
| | Millions of yen | % | Millions of yen | % | Millions of yen | % | Yen |
| Full year | 400 | (6.5) | (1,450) | – | (1,450) | – | (45.13) |

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

* Proper use of earnings forecasts, and other special matters

The forecasts and other forward-looking statements in this report are based on currently available information and certain assumptions determined as rational. Consequently, any statements herein do not constitute assurances regarding actual results by D.Western Therapeutics Institute, Inc. (the “Company”). Actual performance and other results may differ significantly due to various factors. For the suppositions that form the assumptions for financial forecasts and cautions concerning the use thereof, please refer to “(4) Future outlook” of “1. Overview of operating results and others” on page 6 of the attached material to the financial results report. Supplementary materials explaining the financial results are scheduled to be disclosed via TDnet on the same day.

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1. Overview of operating results and others

(1) Overview of operating results for the fiscal year

During the fiscal year ended December 31, 2023, the D.Western Therapeutics Institute Group (“the Group”) promoted its research and development activities with the objective of continuously discovering new drugs and expanding the development pipeline.

Products on the market (GLANATEC® ophthalmic solution 0.4% for glaucoma treatment, GLA-ALPHA® combination ophthalmic solution for glaucoma treatment, ophthalmic surgical adjuvant DW-1002, both as single agent and combination drug) recorded steady sales by licensees. DW-1002 in particular posted year-on-year increase in revenue due to higher sales volume and the impact of the weaker yen.

With regard to the development pipeline, K-321 for Fuchs endothelial corneal dystrophy, a product that has already been out-licensed, began global Phase III clinical trials in March. In May, we applied for approval in China for the use of ophthalmic surgical adjuvant DW-1002 as a single agent, and as a combination drug, we obtained orphan drug designation in the U.S. in July. In March, we reapplied for DW-5LBT, which is a jointly developed neuropathic pain treatment, but because we received a complete response letter in September, we addressed the matters raised by the FDA and reapplied in January 2024. We decided a development plan for regenerative cell therapy product DWR-2206 in July, and are moving forward with preparations for clinical trials. We began administering internally developed H-1337 for glaucoma treatment in Phase IIb clinical trials in the U.S. in August.

In terms of research projects, we promoted research and development activities aimed at exploring new drug candidate compounds primarily for ophthalmic conditions, as well as promoting joint development with other companies.

As result of the above, royalty income, etc. from products on the market drove net sales of ¥428 million (down 4.4% year on year), while cost of sales came to ¥36 million (up 33.0% year on year).

Selling, general and administrative expenses were ¥1,190 million (up 63.8% year on year). The breakdown of selling, general and administrative expenses was research and development expenses of ¥930 million (up 98.2% year on year), associated with increased development expenses of H-1337 and DWR-2206, and other selling, general and administrative expenses of ¥259 million (up 1.1% year on year).

This resulted in operating loss of ¥798 million (compared to operating loss of ¥305 million in the previous fiscal year), and ordinary loss of ¥796 million (compared to ordinary loss of ¥295 million in the previous fiscal year). After recording extraordinary losses of ¥30 million, loss attributable to owners of parent came to ¥812 million (compared to loss attributable to owners of parent of ¥429 million in the previous fiscal year).

The state of new drug candidate compound development in the fiscal year ended December 31, 2023 was as follows.

(i) Product on market

| Product name, etc. | | Clinical indication | Region | Licensee |
|---|--|-------------------------------------|---------------------------------------|----------|
| Ripasudil hydrochloride hydrate | GLANATEC® ophthalmic solution 0.4% | Glaucoma and ocular hypertension | Japan, Asia (Note) | Kowa |
| Ripasudil hydrochloride hydrate/Brimonidine tartrate | GLA-ALPHA® combination ophthalmic solution | Glaucoma and ocular hypertension | Japan | |
| DW-1002 | Brilliant Blue G | ILM-Blue®, TissueBlue™ | ILM staining | DORC |
| | Brilliant Blue G /trypan blue | MembraneBlue- Dual® | ILM, ERM and PVR membrane staining | |
| | | | Europe, etc. | |

Note: Has been launched in certain areas of Asia.

(ii) Development pipeline

| Development code, etc. | | Clinical indication | Development stage | Region | Licensee |
|------------------------|---------------------------------|--|---------------------------|--------------------|-----------------------------------|
| K-321 | Ripasudil hydrochloride hydrate | Fuchs endothelial corneal dystrophy | Phase III clinical trials | U.S., Europe, etc. | Kowa |
| DW-1002 | Brilliant Blue G | ILM staining | Application | China | DORC |
| | | | Phase III clinical trials | Japan | Wakamoto Pharmaceutical |
| | ALC staining | Phase III clinical trials | Japan | | |
| | Brilliant Blue G /trypan blue | ILM staining and ERM staining | In preparation for filing | U.S. | DORC |
| DW-1001 | | Ophthalmic treatment agent (undisclosed) | Phase I clinical trials | Japan | ROHTO Pharmaceutical |
| H-1337 | | Glaucoma and ocular hypertension | Phase IIb clinical trials | U.S. | Developed internally |
| DW-5LBT | | Neuropathic pain after shingles | Application | U.S. | Jointly developed with MEDRx |
| DWR-2206 | | Bullous Keratopathy | Non-clinical studies | Japan | Jointly developed with ActualEyes |

(A) Ripasudil hydrochloride hydrate

- (a) GLANATEC® ophthalmic solution 0.4% (clinical indication: glaucoma and ocular hypertension)

This product is an isoquinoline sulfonamide compound that selectively inhibits Rho-kinase, which is a type of protein kinase, acting to lower intraocular pressure and enabling it to be used as an ophthalmic solution for treating glaucoma and ocular hypertension. This is the first product using the mechanism of action for glaucoma treatment anywhere in the world, with intraocular pressure lowered by inhibiting Rho-kinase to promote the outflow of aqueous humor from the main collector channel via the trabecular meshwork/Schlemm's canal.

The Company out-licensed global rights to the product to Kowa Company, Ltd. ("Kowa") in 2002. Kowa subsequently proceeded with clinical trials, and the product was launched in the domestic market as an indication for glaucoma and ocular hypertension in 2014. Moreover, Kowa has moved ahead with overseas expansion, and the product has been launched in certain areas of Asia.

- (b) K-321 (clinical indication: Fuchs endothelial corneal dystrophy)

There are suggestions that GLANATEC®, which is a Rho-kinase inhibitor, may act on kinase within the eye, and the possibility of indications for other ophthalmic conditions is being investigated. As an initiative to expand indications, an investigational new drug (IND) application for Phase II clinical trials was submitted in the U.S. in 2019, and Kowa performed trials for an indication for Fuchs endothelial corneal dystrophy. Phase III clinical trials were subsequently begun in the U.S. in 2022, and global (including the U.S.) Phase III clinical trials were begun in March 2023. As Fuchs endothelial corneal dystrophy progresses, it leads to corneal endothelial disorders. Treatment for patients with corneal endothelial conditions resulting in serious vision impairment has hitherto been limited to corneal transplants, making it desirable to develop effective drugs.

- (c) GLA-ALPHA[®] combination ophthalmic solution (clinical indication: glaucoma and ocular hypertension)

This product was the first combination ophthalmic solution in the world to contain both ripasudil hydrochloride hydrate and brimonidine tartrate. In 2020 Kowa began conducting Phase III clinical trials in Japan as an indication for glaucoma and ocular hypertension, and the product was launched in the Japanese market in 2022. It is becoming standard practice in the treatment of glaucoma to use multiple drug combinations. This product is expected to lead to improved adherence, and we believe it will make a positive contribution to the treatment of glaucoma patients.

- (B) DW-1002 (single agent clinical indications: ILM staining, ALC staining; combination drug clinical indications: ILM, ERM and PVR membrane staining)

This product, which is being developed under an exclusive license, is an ophthalmic surgical adjuvant whose active ingredient is BBG250 (Brilliant Blue G-250), a dye with excellent staining properties that was discovered by a research group at Kyushu University. By temporarily and safely dyeing the internal limiting membrane within the eye or the anterior lens capsule, it facilitates vitrectomy or cataract surgery. The Company received transfer of this business in 2017.

We granted an exclusive sublicense globally outside Japan to Dutch Ophthalmic Research Center International B.V. (“DORC”), and since 2010 DORC has been engaged in the manufacture and sale in Europe, etc. of single agents for ILM staining during vitrectomy (Brilliant Blue G) and combination drugs for ILM, ERM, and PVR membrane staining during vitrectomy (Brilliant Blue G/trypan blue). In 2020, it also began selling a single agent in the U.S., and as of today, it sells its products in 76 countries and regions around the world, including those of Europe, and the U.S. In May 2023, an application for the single agent was applied for in China, and in July, the combination drug was designated as an orphan drug for ILM and ERM in the U.S.

In Japan, we have granted an exclusive sublicense to WAKAMOTO PHARMACEUTICAL CO., LTD. (“Wakamoto Pharmaceutical”), which is proceeding with development with the objective of obtaining manufacturing and sales approval for ILM staining during vitrectomy, and for ALC staining during cataract surgery.

- (C) DW-1001 (clinical indication: undisclosed)

This product was in-licensed as an ophthalmic treatment agent from a U.K. company in 2015.

This compound is already on the market as an indication for other diseases, and by taking a so-called repositioning approach to development in order to expand indications to ophthalmology, we expect to reduce development costs and risks to relatively low levels.

In 2019, we granted an exclusive license in Japan to ROHTO Pharmaceutical Co., Ltd. (“ROHTO Pharmaceutical”). ROHTO Pharmaceutical proceeded with non-clinical studies, and concluded Phase I clinical trials in Japan in 2022, having obtained favorable results. It is currently moving forward with preparations for Phase II clinical trials in Japan.

- (D) H-1337 (clinical indication: glaucoma and ocular hypertension)

This is an optimized product based on seed compounds from the Company’s library of compounds centered on protein kinase inhibitors, and is designed for the clinical indication of glaucoma and ocular hypertension. This was our first internal clinical development, and we concluded Phase I/Phase IIa clinical trials in the U.S. in 2018. Having obtained favorable results, we confirmed the efficacy of the product in terms of primary endpoints, and with regard to safety, no critical adverse events were recognized. In August 2023, we began administering it in Phase IIb clinical trials in the U.S.

We are proceeding with research to expand indications, and therapeutic effects for wet age-related macular degeneration and pulmonary hypertension have been confirmed in animal testing.

(E) DW-5LBT (clinical indication: neuropathic pain after shingles)

This product is a new lidocaine tape that uses the proprietary ILTS (Ionic Liquid Transdermal System) developed by MEDRx Co., Ltd. (“MEDRx”), and we are proceeding with development that targets the lidocaine patch market occupied by Lidoderm. MEDRx has been moving forward with development focused on treatment of neuropathic pain after shingles, and we began joint development with them in 2020. In 2020, we applied for approval from the FDA (the U.S. Food and Drug Administration), but in 2021, we received a complete response letter. The additional trials that were indicated as being necessary to obtain approval produced favorable results, and we reapplied in March 2023. However, because we received a complete response letter in September, we addressed the matters raised by the FDA and reapplied in January 2024.

(F) DWR-2206 (clinical indication: bullous keratopathy)

This is a regenerative cell therapy product for bullous keratopathy. Cultured human corneal endothelial cells and a suspension containing ROCK inhibitor are injected into the anterior chamber of the eye to regenerate the corneal endothelium. ActualEyes has been proceeding with development, and we began joint development with them in 2022. This is our first regenerative treatment, and we are currently preparing for clinical trials in Japan.

(iii) Research projects

The Group is engaged in the discovery of new drug candidate compounds with a focus on protein kinase inhibitors. There are various diseases in which protein kinases are relevant, but we are promoting research with a focus on ophthalmic conditions in particular. Leveraging our drug discovery platform technology, we are actively promoting alliances with other companies.

Our main project consists of the development of signal transmission inhibitors at our research institute (in the research facilities of Mie University) for treatment of ophthalmic, neuropathic, and respiratory conditions. In terms of joint development, we are forging ahead with multiple initiatives, such as a targeted protein degradation project with UBiENCE Inc., and an ophthalmic condition drug discovery project with RaQualia Pharma Inc.

(2) Overview of financial position for the fiscal year

Total assets decreased by ¥583 million from the end of the previous fiscal year to ¥2,373 million. Current assets decreased by ¥521 million from the end of the previous fiscal year to ¥2,137 million. The main factors were decreases of ¥467 million in cash and deposits and ¥53 million in accounts receivable - trade. Non-current assets decreased by ¥61 million from the end of the previous fiscal year to ¥235 million. The main factors were decreases of ¥41 million in contract-related intangible assets and ¥12 million in investment securities.

Liabilities increased by ¥10 million from the end of the previous fiscal year to ¥1,093 million. Current liabilities decreased by ¥17 million from the end of the previous fiscal year to ¥194 million. The main factors were a decrease of ¥110 million in current portion of long-term borrowings, despite an increase of ¥97 million in accounts payable - others. Non-current liabilities increased by ¥27 million from the end of the previous fiscal year to ¥899 million. The factors were an increase of ¥156 million in long-term borrowings, despite a decrease of ¥128 million in convertible-bond-type bonds with share acquisition rights.

Net assets decreased by ¥593 million from the end of the previous fiscal year to ¥1,279 million. The main factors were a decrease in retained earnings of ¥812 million caused by the recording of loss attributable to owners of parent and other factors, despite increases of ¥117 million in share capital and ¥117 million in capital surplus, as a result of the conversion of convertible-bond-type bonds with share acquisition rights and the exercise of share acquisition rights.

As a result, the equity ratio was 53.9%.

(3) Overview of cash flows for the fiscal year

Cash and cash equivalents (“cash”) as of December 31, 2023 decreased by ¥467 million from December 31, 2022 to ¥1,867 million.

The status of cash flows and their factors during the fiscal year ended December 31, 2023 are as follows.

Cash flows from operating activities

Net cash used in operating activities amounted to ¥586 million (¥354 million used in the previous fiscal year). This was mainly due to loss before income taxes of ¥826 million, despite an increase in accounts payable - other of ¥95 million and a decrease in trade receivables of ¥53 million.

Cash flows from investing activities

Net cash used in investing activities amounted to ¥15 million (¥139 million used in the previous fiscal year). This was mainly due to purchase of property, plant and equipment of ¥12 million.

Cash flows from financing activities

Net cash provided by financing activities amounted to ¥134 million (¥867 million provided in the previous fiscal year). This was mainly due to proceeds from long-term borrowings of ¥166 million and proceeds from issuance of shares resulting from exercise of share acquisition rights of ¥88 million, despite repayments of long-term borrowings of ¥120 million.

(4) Future outlook

As a result of royalty income from products on the market and milestone income related to DW-1002, we forecast net sales of ¥400 million (compared to net sales of ¥428 million in the fiscal year ended December 31, 2023).

In addition to usual research activities aimed at discovering new drug candidates, we expect expenses related to Phase IIb clinical trials for H-1337 in the U.S., development expenses for DWR-2206, and milestone payments associated with obtaining approval for DW-5LBT, and accordingly forecast research and development expenses of ¥1,600 million (compared to research and development expenses of ¥930 million in the fiscal year ended December 31, 2023).

As a result, we forecast operating loss of ¥1,500 million (compared to operating loss of ¥798 million in the fiscal year ended December 31, 2023), ordinary loss of ¥1,510 million (compared to ordinary loss of ¥796 million in the fiscal year ended December 31, 2023), and loss attributable to owners of parent of ¥1,510 million (compared to loss attributable to owners of parent of ¥812 million in the fiscal year ended December 31, 2023).

(5) Significant events regarding premise of going concern

Due to the nature of its business, the Group incurs expenses for drug discovery research and clinical development before generating earnings, and therefore continuously posts operating losses and generates negative operating cash flow, and has events and situations that can cause material doubts regarding the premise of going concern.

To eliminate such situations, the Group works to achieve early market launches through steady progress on development in its development pipeline and to capture further earnings opportunities through expansion of its development pipeline. In addition, the Group will secure the necessary funds for research and development by advancing with its current fund procurement, and will consider conducting new fund procurement and so forth as necessary.

On the cash front, at the end of the current fiscal year, the Company’s cash and deposits stood at ¥1,867 million, sufficient cash to fund the next fiscal year of business activities, as a result of continuous royalty income and development expenditure control as well as timely fund procurement conducted through good relationships with main financial institutions and investment companies.

As a result of the above, the Company recognizes that there are no material uncertainties regarding the premise of going concern.

2. Basic rationale for selection of accounting standards

To ensure comparability among companies and with past years, the Group prepares its consolidated financial statements in accordance with the “Regulation on Terminology, Forms, and Preparation Methods of Consolidated Financial Statements (excluding Chapters VII and VIII)” (Ministry of Finance Order No. 28 of 1976). With respect to adoption of International Financial Reporting Standards (IFRS), the Group will follow a policy of responding in a suitable manner after giving consideration to various circumstances in Japan and overseas.

3. Consolidated financial statements and significant notes thereto

(1) Consolidated balance sheets

(Thousands of yen)

| | As of December 31, 2022 | As of December 31, 2023 |
|---|-------------------------|-------------------------|
| Assets | | |
| Current assets | | |
| Cash and deposits | 2,334,668 | 1,867,264 |
| Accounts receivable - trade | 170,755 | 117,144 |
| Supplies | 79,211 | 87,863 |
| Other | 74,436 | 65,687 |
| Total current assets | 2,659,072 | 2,137,959 |
| Non-current assets | | |
| Property, plant and equipment | | |
| Buildings | 8,727 | 8,727 |
| Accumulated depreciation | (4,968) | (5,210) |
| Buildings, net | 3,758 | 3,516 |
| Tools, furniture and fixtures | 97,052 | 102,666 |
| Accumulated depreciation | (90,706) | (96,172) |
| Tools, furniture and fixtures, net | 6,346 | 6,493 |
| Total property, plant and equipment | 10,105 | 10,010 |
| Intangible assets | | |
| Contract-related intangible assets | 123,428 | 82,285 |
| Other | 1,101 | 4,224 |
| Total intangible assets | 124,529 | 86,510 |
| Investments and other assets | | |
| Investment securities | 153,551 | 141,501 |
| Other | 9,117 | 8,690 |
| Allowance for doubtful accounts | – | (11,301) |
| Total investments and other assets | 162,668 | 138,890 |
| Total non-current assets | 297,303 | 235,411 |
| Total assets | 2,956,376 | 2,373,371 |
| Liabilities | | |
| Current liabilities | | |
| Current portion of long-term borrowings | 120,000 | 9,524 |
| Accounts payable - other | 64,210 | 161,362 |
| Income taxes payable | 11,234 | 11,708 |
| Other | 15,762 | 11,412 |
| Total current liabilities | 211,207 | 194,008 |
| Non-current liabilities | | |
| Convertible-bond-type bonds with share acquisition rights | 734,693 | 606,122 |
| Long-term borrowings | 113,000 | 269,476 |
| Other | 24,000 | 24,000 |
| Total non-current liabilities | 871,693 | 899,598 |
| Total liabilities | 1,082,900 | 1,093,606 |

(Thousands of yen)

| | As of December 31, 2022 | As of December 31, 2023 |
|---|-------------------------|-------------------------|
| Net assets | | |
| Shareholders' equity | | |
| Share capital | 714,244 | 831,617 |
| Capital surplus | 2,772,484 | 2,889,857 |
| Retained earnings | (1,629,961) | (2,442,372) |
| Treasury shares | – | (0) |
| Total shareholders' equity | 1,856,767 | 1,279,101 |
| Accumulated other comprehensive income | | |
| Valuation difference on available-for-sale securities | (222) | (36) |
| Total accumulated other comprehensive income | (222) | (36) |
| Share acquisition rights | 943 | 699 |
| Non-controlling interests | 15,987 | – |
| Total net assets | 1,873,475 | 1,279,764 |
| Total liabilities and net assets | 2,956,376 | 2,373,371 |

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

(Thousands of yen)

| | Fiscal year ended December 31, 2022 | Fiscal year ended December 31, 2023 |
|--|--|--|
| Net sales | 448,100 | 428,364 |
| Cost of sales | 27,566 | 36,666 |
| Gross profit | 420,533 | 391,697 |
| Selling, general and administrative expenses | | |
| Research and development expenses | 469,564 | 930,506 |
| Other | 256,881 | 259,749 |
| Total selling, general and administrative expenses | 726,446 | 1,190,256 |
| Operating loss | (305,912) | (798,558) |
| Non-operating income | | |
| Interest income | 25 | 10 |
| Foreign exchange gains | 33,278 | 6,713 |
| Other | 5,185 | 11 |
| Total non-operating income | 38,489 | 6,735 |
| Non-operating expenses | | |
| Interest expenses | 3,147 | 2,490 |
| Commission expenses | 13,521 | 483 |
| Share issuance costs | 889 | 1,396 |
| Share issuance costs | 10,825 | – |
| Other | – | 170 |
| Total non-operating expenses | 28,384 | 4,540 |
| Ordinary loss | (295,806) | (796,363) |
| Extraordinary losses | | |
| Loss on valuation of investment securities | 100,319 | 12,992 |
| Provision of allowance for doubtful accounts | – | 11,301 |
| Impairment losses | – | 6,146 |
| Settlement money | 44,140 | – |
| Total extraordinary losses | 144,460 | 30,439 |
| Loss before income taxes | (440,267) | (826,803) |
| Income taxes - current | 1,595 | 1,595 |
| Total income taxes | 1,595 | 1,595 |
| Loss | (441,863) | (828,398) |
| Loss attributable to non-controlling interests | (12,177) | (15,987) |
| Loss attributable to owners of parent | (429,685) | (812,411) |

Consolidated statements of comprehensive income

(Thousands of yen)

| | Fiscal year ended December 31, 2022 | Fiscal year ended December 31, 2023 |
|--|--|--|
| Loss | (441,863) | (828,398) |
| Other comprehensive income | | |
| Valuation difference on available-for-sale securities | (222) | (36) |
| Total other comprehensive income | (222) | (36) |
| Comprehensive income | (442,085) | (828,435) |
| Comprehensive income attributable to | | |
| Comprehensive income attributable to owners of parent | (429,908) | (812,448) |
| Comprehensive income attributable to non-controlling interests | (12,177) | (15,987) |

(3) Consolidated statements of changes in equity

Fiscal year ended December 31, 2022

(Thousands of yen)

| | Shareholders' equity | | | |
|--|----------------------|-----------------|-------------------|----------------------------|
| | Share capital | Capital surplus | Retained earnings | Total shareholders' equity |
| Balance at beginning of period | 573,159 | 2,631,398 | (1,200,276) | 2,004,281 |
| Changes during period | | | | |
| Issuance of new shares | 141,085 | 141,085 | | 282,171 |
| Loss attributable to owners of parent | | | (429,685) | (429,685) |
| Net changes in items other than shareholders' equity | | | | |
| Total changes during period | 141,085 | 141,085 | (429,685) | (147,514) |
| Balance at end of period | 714,244 | 2,772,484 | (1,629,961) | 1,856,767 |

| | Accumulated other comprehensive income | | Share acquisition rights | Non-controlling interests | Total net assets |
|--|---|--|--------------------------|---------------------------|------------------|
| | Valuation difference on available-for-sale securities | Total accumulated other comprehensive income | | | |
| Balance at beginning of period | – | – | 2,692 | 28,164 | 2,035,138 |
| Changes during period | | | | | |
| Issuance of new shares | | | | | 282,171 |
| Loss attributable to owners of parent | | | | | (429,685) |
| Net changes in items other than shareholders' equity | (222) | (222) | (1,748) | (12,177) | (14,148) |
| Total changes during period | (222) | (222) | (1,748) | (12,177) | (161,663) |
| Balance at end of period | (222) | (222) | 943 | 15,987 | 1,873,475 |

Fiscal year ended December 31, 2023

(Thousands of yen)

| | Shareholders' equity | | | | |
|--|----------------------|-----------------|-------------------|-----------------|----------------------------|
| | Share capital | Capital surplus | Retained earnings | Treasury shares | Total shareholders' equity |
| Balance at beginning of period | 714,244 | 2,772,484 | (1,629,961) | – | 1,856,767 |
| Changes during period | | | | | |
| Issuance of new shares | 117,373 | 117,373 | | | 234,746 |
| Loss attributable to owners of parent | | | (812,411) | | (812,411) |
| Purchase of treasury shares | | | | (0) | (0) |
| Net changes in items other than shareholders' equity | | | | | |
| Total changes during period | 117,373 | 117,373 | (812,411) | (0) | (577,665) |
| Balance at end of period | 831,617 | 2,889,857 | (2,442,372) | (0) | 1,279,101 |

| | Accumulated other comprehensive income | | Share acquisition rights | Non-controlling interests | Total net assets |
|--|---|--|--------------------------|---------------------------|------------------|
| | Valuation difference on available-for-sale securities | Total accumulated other comprehensive income | | | |
| Balance at beginning of period | (222) | (222) | 943 | 15,987 | 1,873,475 |
| Changes during period | | | | | |
| Issuance of new shares | | | | | 234,746 |
| Loss attributable to owners of parent | | | | | (812,411) |
| Purchase of treasury shares | | | | | (0) |
| Net changes in items other than shareholders' equity | 185 | 185 | (244) | (15,987) | (16,045) |
| Total changes during period | 185 | 185 | (244) | (15,987) | (593,711) |
| Balance at end of period | (36) | (36) | 699 | – | 1,279,764 |

(4) Consolidated statements of cash flows

(Thousands of yen)

| | Fiscal year ended December 31, 2022 | Fiscal year ended December 31, 2023 |
|--|--|--|
| Cash flows from operating activities | | |
| Loss before income taxes | (440,267) | (826,803) |
| Depreciation | 46,366 | 48,721 |
| Impairment losses | – | 6,146 |
| Increase (decrease) in allowance for doubtful accounts | – | 11,301 |
| Share-based payment expenses | 15,811 | 15,569 |
| Settlement money | 44,140 | – |
| Interest income | (25) | (10) |
| Interest expenses | 3,147 | 2,490 |
| Commission expenses | 13,521 | 483 |
| Foreign exchange losses (gains) | (29,669) | (961) |
| Share issuance costs | 889 | 1,396 |
| Share issuance costs | 10,825 | – |
| Loss (gain) on valuation of investment securities | 100,319 | 12,992 |
| Decrease (increase) in trade receivables | (113,221) | 53,610 |
| Decrease (increase) in inventories | 9,187 | 22,594 |
| Increase (decrease) in accounts payable - other | 22,450 | 95,242 |
| Other, net | (33,838) | (25,855) |
| Subtotal | (350,360) | (583,081) |
| Interest and dividends received | 25 | 10 |
| Interest paid | (2,839) | (2,158) |
| Income taxes paid | (1,596) | (1,593) |
| Net cash provided by (used in) operating activities | (354,770) | (586,821) |
| Cash flows from investing activities | | |
| Purchase of property, plant and equipment | (9,614) | (12,026) |
| Purchase of intangible assets | (200) | (2,912) |
| Purchase of investment securities | (130,200) | – |
| Decrease (increase) in guarantee deposits | 124 | (316) |
| Net cash provided by (used in) investing activities | (139,890) | (15,254) |
| Cash flows from financing activities | | |
| Proceeds from long-term borrowings | 13,000 | 166,000 |
| Repayments of long-term borrowings | (120,000) | (120,000) |
| Proceeds from issuance of convertible-bond-type bonds with share acquisition rights | 900,000 | – |
| Proceeds from issuance of share acquisition rights | 1,216 | – |
| Proceeds from issuance of shares resulting from exercise of share acquisition rights | 99,898 | 88,994 |
| Payments for issuance of shares | (10,825) | – |
| Purchase of treasury shares | – | (0) |
| Purchase of treasury share acquisition rights | (2,692) | – |
| Commission expenses paid | (13,200) | (527) |
| Other, net | (99) | – |
| Net cash provided by (used in) financing activities | 867,297 | 134,466 |
| Effect of exchange rate change on cash and cash equivalents | 28,289 | 205 |
| Net increase (decrease) in cash and cash equivalents | 400,924 | (467,404) |
| Cash and cash equivalents at beginning of period | 1,933,743 | 2,334,668 |
| Cash and cash equivalents at end of period | 2,334,668 | 1,867,264 |

(5) Notes to consolidated financial statements
(Notes on premise of going concern)

Not applicable.

(Segment information)

This information is omitted as the Group operates a single segment of the drug discovery business.

[Related information]

Fiscal year ended December 31, 2022 (from January 1, 2022 to December 31, 2022)

1. Information about products and services

This information is omitted as net sales to external customers in a single product/service category exceed 90% of net sales in the consolidated statement of income.

2. Information about geographical areas

(1) Net sales

| (Thousands of yen) | | |
|--------------------|-------------|---------|
| Japan | Netherlands | Total |
| 227,438 | 220,662 | 448,100 |

Note: Net sales are classified by country based on customers' location.

(2) Property, plant and equipment

This information is omitted as there are no property, plant and equipment located outside Japan.

3. Information about main customers

| (Thousands of yen) | |
|---|-----------|
| Customer name | Net sales |
| Dutch Ophthalmic Research Center International B.V. | 220,662 |
| Kowa Company, Ltd. | 170,924 |

Note: The related segment name is not presented because the Company operates a single segment.

Fiscal year ended December 31, 2023 (from January 1, 2023 to December 31, 2023)

1. Information about products and services

This information is omitted as net sales to external customers in a single product/service category exceed 90% of net sales in the consolidated statement of income.

2. Information about geographical areas

(1) Net sales

| (Thousands of yen) | | | |
|--------------------|---------|-------|---------|
| Netherlands | Japan | Other | Total |
| 277,698 | 150,640 | 25 | 428,364 |

Note: Net sales are classified by country based on customers' location.

(2) Property, plant and equipment

This information is omitted as there are no property, plant and equipment located outside Japan.

3. Information about main customers

(Thousands of yen)

| Customer name | Net sales |
|---|-----------|
| Dutch Ophthalmic Research Center International B.V. | 277,698 |
| Kowa Company, Ltd. | 140,336 |

Note: The related segment name is not presented because the Company operates a single segment.

[Information about impairment loss of non-current assets by reportable segment]

Fiscal year ended December 31, 2022 (from January 1, 2022 to December 31, 2022)

Not applicable.

Fiscal year ended December 31, 2023 (from January 1, 2023 to December 31, 2023)

This information is omitted as the Group operates a single segment of the drug discovery business.

[Information about amortization and unamortized balance of goodwill by reportable segment]

Not applicable.

[Information about gain on bargain purchase by reportable segment]

Not applicable.

(Per share information)

(Yen)

| | Fiscal year ended December 31, 2022 (from January 1, 2022 to December 31, 2022) | Fiscal year ended December 31, 2023 (from January 1, 2023 to December 31, 2023) |
|----------------------|---|---|
| Net assets per share | 60.14 | 39.81 |
| Loss per share | (14.50) | (25.56) |

Notes: 1. Although potential shares exist, diluted earnings per share is not presented due to loss per share having been recorded.

2. The basis for calculation of loss per share is as follows.

| | Fiscal year ended December 31, 2022 (from January 1, 2022 to December 31, 2022) | Fiscal year ended December 31, 2023 (from January 1, 2023 to December 31, 2023) |
|---|---|---|
| Loss attributable to owners of parent (Thousands of yen) | (429,685) | (812,411) |
| Value not attributable to shareholders of common shares (Thousands of yen) | — | — |
| Loss attributable to owners of parent related to common shares (Thousands of yen) | (429,685) | (812,411) |
| Average number of shares outstanding during the period (Shares) | 29,639,914 | 31,780,063 |
| Overview of potential shares not included in the calculation of the diluted earnings per share because of the lack of dilution effects | — | — |

(Subsequent events)

Not applicable.

4. Non-consolidated financial statements and significant notes thereto

(1) Non-consolidated balance sheets

(Thousands of yen)

| | As of December 31, 2022 | As of December 31, 2023 |
|--|-------------------------|-------------------------|
| Assets | | |
| Current assets | | |
| Cash and deposits | 2,159,720 | 1,754,446 |
| Accounts receivable - trade | 170,167 | 117,144 |
| Supplies | 76,458 | 85,107 |
| Advance payments to suppliers | 48,565 | 33,292 |
| Prepaid expenses | 9,610 | 17,269 |
| Short-term loans receivable from subsidiaries and associates | 100,000 | 100,000 |
| Other | 12,988 | 29,087 |
| Total current assets | 2,577,511 | 2,136,347 |
| Non-current assets | | |
| Property, plant and equipment | | |
| Buildings | 3,758 | 3,516 |
| Tools, furniture and fixtures | 5,453 | 6,493 |
| Total property, plant and equipment | 9,212 | 10,010 |
| Intangible assets | | |
| Software | 986 | 4,151 |
| Contract-related intangible assets | 123,428 | 82,285 |
| Other | 72 | 72 |
| Total intangible assets | 124,487 | 86,510 |
| Investments and other assets | | |
| Investment securities | 153,551 | 141,501 |
| Shares of subsidiaries and associates | 99,279 | 0 |
| Other | 9,117 | 8,690 |
| Allowance for doubtful accounts | – | (11,301) |
| Total investments and other assets | 261,947 | 138,890 |
| Total non-current assets | 395,648 | 235,411 |
| Total assets | 2,973,159 | 2,371,758 |
| Liabilities | | |
| Current liabilities | | |
| Current portion of long-term borrowings | 120,000 | 9,524 |
| Accounts payable - other | 62,632 | 161,034 |
| Accrued expenses | 4,741 | 5,786 |
| Income taxes payable | 10,616 | 11,090 |
| Deposits received | 3,061 | 2,828 |
| Total current liabilities | 201,051 | 190,263 |
| Non-current liabilities | | |
| Convertible-bond-type bonds with share acquisition rights | 734,693 | 606,122 |
| Long-term borrowings | 113,000 | 269,476 |
| Other | 24,000 | 24,000 |
| Total non-current liabilities | 871,693 | 899,598 |
| Total liabilities | 1,072,745 | 1,089,862 |

(Thousands of yen)

| | As of December 31, 2022 | As of December 31, 2023 |
|---|-------------------------|-------------------------|
| Net assets | | |
| Shareholders' equity | | |
| Share capital | 714,244 | 831,617 |
| Capital surplus | | |
| Legal capital surplus | 2,813,586 | 2,930,959 |
| Total capital surplus | 2,813,586 | 2,930,959 |
| Retained earnings | | |
| Other retained earnings | | |
| Retained earnings brought forward | (1,628,138) | (2,481,343) |
| Total retained earnings | (1,628,138) | (2,481,343) |
| Treasury shares | – | (0) |
| Total shareholders' equity | 1,899,692 | 1,281,233 |
| Valuation and translation adjustments | | |
| Valuation difference on available-for-sale securities | (222) | (36) |
| Total valuation and translation adjustments | (222) | (36) |
| Share acquisition rights | 943 | 699 |
| Total net assets | 1,900,413 | 1,281,896 |
| Total liabilities and net assets | 2,973,159 | 2,371,758 |

(2) Non-consolidated statements of income

(Thousands of yen)

| | Fiscal year ended December 31, 2022 | Fiscal year ended December 31, 2023 |
|--|--|--|
| Net sales | 411,586 | 427,968 |
| Cost of sales | 27,145 | 36,666 |
| Gross profit | 384,440 | 391,301 |
| Selling, general and administrative expenses | | |
| Research and development expenses | 411,250 | 895,142 |
| Other | 228,207 | 231,645 |
| Total selling, general and administrative expenses | 639,458 | 1,126,787 |
| Operating loss | (255,017) | (735,486) |
| Non-operating income | | |
| Interest income | 1,023 | 1,009 |
| Foreign exchange gains | 33,278 | 6,713 |
| Commission income | 3,600 | 3,600 |
| Other | 4,177 | 5 |
| Total non-operating income | 42,078 | 11,328 |
| Non-operating expenses | | |
| Interest expenses | 3,147 | 2,490 |
| Commission expenses | 13,521 | 483 |
| Share issuance costs | 889 | 1,396 |
| Share issuance costs | 10,825 | - |
| Other | - | 127 |
| Total non-operating expenses | 28,384 | 4,497 |
| Ordinary loss | (241,322) | (728,655) |
| Extraordinary losses | | |
| Loss on valuation of investment securities | 100,319 | 12,992 |
| Provision of allowance for doubtful accounts | - | 11,301 |
| Settlement money | 44,140 | - |
| Loss on valuation of shares of subsidiaries and associates | - | 99,278 |
| Total extraordinary losses | 144,460 | 123,572 |
| Loss before income taxes | (385,783) | (852,228) |
| Income taxes - current | 977 | 977 |
| Total income taxes | 977 | 977 |
| Loss | (386,760) | (853,205) |

(3) Non-consolidated statements of changes in equity

Fiscal year ended December 31, 2022

(Thousands of yen)

| | Shareholders' equity | | | | | |
|--|----------------------|-----------------------|-----------------------|--|-------------------------|----------------------------|
| | Share capital | Capital surplus | | Retained earnings | | Total shareholders' equity |
| | | Legal capital surplus | Total capital surplus | Other retained earnings Retained earnings brought forward | Total retained earnings | |
| Balance at beginning of period | 573,159 | 2,672,501 | 2,672,501 | (1,241,378) | (1,241,378) | 2,004,282 |
| Changes during period | | | | | | |
| Issuance of new shares | 141,085 | 141,085 | 141,085 | | | 282,171 |
| Loss | | | | (386,760) | (386,760) | (386,760) |
| Net changes in items other than shareholders' equity | | | | | | |
| Total changes during period | 141,085 | 141,085 | 141,085 | (386,760) | (386,760) | (104,589) |
| Balance at end of period | 714,244 | 2,813,586 | 2,813,586 | (1,628,138) | (1,628,138) | 1,899,692 |

| | Valuation and translation adjustments | | Share acquisition rights | Total net assets |
|--|---|---|--------------------------|------------------|
| | Valuation difference on available-for-sale securities | Total valuation and translation adjustments | | |
| Balance at beginning of period | – | – | 2,692 | 2,006,974 |
| Changes during period | | | | |
| Issuance of new shares | | | | 282,171 |
| Loss | | | | (386,760) |
| Net changes in items other than shareholders' equity | (222) | (222) | (1,748) | (1,971) |
| Total changes during period | (222) | (222) | (1,748) | (106,560) |
| Balance at end of period | (222) | (222) | 943 | 1,900,413 |

Fiscal year ended December 31, 2023

(Thousands of yen)

| | Shareholders' equity | | | | | | |
|--|----------------------|-----------------------|-----------------------|--|-------------------------|-----------------|----------------------------|
| | Share capital | Capital surplus | | Retained earnings | | Treasury shares | Total shareholders' equity |
| | | Legal capital surplus | Total capital surplus | Other retained earnings Retained earnings brought forward | Total retained earnings | | |
| Balance at beginning of period | 714,244 | 2,813,586 | 2,813,586 | (1,628,138) | (1,628,138) | – | 1,899,692 |
| Changes during period | | | | | | | |
| Issuance of new shares | 117,373 | 117,373 | 117,373 | | | | 234,746 |
| Loss | | | | (853,205) | (853,205) | | (853,205) |
| Purchase of treasury shares | | | | | | (0) | (0) |
| Net changes in items other than shareholders' equity | | | | | | | |
| Total changes during period | 117,373 | 117,373 | 117,373 | (853,205) | (853,205) | (0) | (618,459) |
| Balance at end of period | 831,617 | 2,930,959 | 2,930,959 | (2,481,343) | (2,481,343) | (0) | 1,281,233 |

| | Valuation and translation adjustments | | Share acquisition rights | Total net assets |
|--|---|---|--------------------------|------------------|
| | Valuation difference on available-for-sale securities | Total valuation and translation adjustments | | |
| Balance at beginning of period | (222) | (222) | 943 | 1,900,413 |
| Changes during period | | | | |
| Issuance of new shares | | | | 234,746 |
| Loss | | | | (853,205) |
| Purchase of treasury shares | | | | (0) |
| Net changes in items other than shareholders' equity | 185 | 185 | (244) | (58) |
| Total changes during period | 185 | 185 | (244) | (618,517) |
| Balance at end of period | (36) | (36) | 699 | 1,281,896 |