Translation

Note: This document has been translated from the Japanese original for reference purposes only. In the event of any discrepancy between this translated document and the Japanese original, the original shall prevail.

February 10, 2025

Consolidated Financial Results for the Fiscal Year Ended December 31, 2024 (Based on Japanese GAAP)

Company name: D.Western Therapeutics Institute, Inc.
Listing: Tokyo
Securities code: 4576
URL: https://www.dwti.co.jp
Representative: Yuichi Hidaka, President and CEO
Inquiries: Sayako Matsubara, Director
TEL: +81-52-218-8785

Scheduled date of ordinary general meeting of shareholders: March 25, 2025
Scheduled date to commence dividend payments: –
Scheduled date to file securities report: March 25, 2025
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, 2024 (from January 1, 2024 to December 31, 2024)

(1) Consolidated operating results

(Percentages indicate year-on-year changes.)

	Net sales		Operating profit		Ordinary profit		Profit attributable to owners of parent	
Fiscal year ended	Millions of yen	%	Millions of yen	%	Millions of yen	%	Millions of yen	%
December 31, 2024	471	10.1	(1,209)	–	(1,228)	–	(1,290)	–
December 31, 2023	428	(4.4)	(798)	–	(796)	–	(812)	–

Note: Comprehensive income For the fiscal year ended December 31, 2024 ¥(1,290) million [–%]
For the fiscal year ended December 31, 2023 ¥(828) million [–%]

	Earnings per share	Diluted earnings per share	Profit attributable to owners of parent/equity	Ordinary profit/ total assets	Operating profit/ net sales
Fiscal year ended	Yen	Yen	%	%	%
December 31, 2024	(36.74)	–	(128.3)	(60.8)	(256.5)
December 31, 2023	(25.56)	–	(51.8)	(29.9)	(186.4)

Reference: Share of profit (loss) of entities accounted for using equity method
For the fiscal year ended December 31, 2024 ¥– million
For the fiscal year ended December 31, 2023 ¥– 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, 2024	1,669	733	43.9	17.59
December 31, 2023	2,373	1,279	53.9	39.81

Reference: Equity
As of December 31, 2024 ¥732 million
As of December 31, 2023 ¥1,279 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, 2024	(1,299)	(10)	567	1,126
December 31, 2023	(586)	(15)	134	1,867

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			
	Yen	Yen	Yen	Yen	Yen	Millions of yen	%	%
Fiscal year ended December 31, 2023	–	0.00	–	0.00	0.00	–	–	–
Fiscal year ended December 31, 2024	–	0.00	–	0.00	0.00	–	–	–
Fiscal year ending December 31, 2025 (Forecast)	–	0.00	–	0.00	0.00		–	

3. Forecast of consolidated financial results for the fiscal year ending December 31, 2025 (from January 1, 2025 to December 31, 2025)

(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	(15.2)	(670)	–	(680)	–	(680)	–	(15.88)

*** Notes**

(1) Significant changes in the scope of consolidation during the period: 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, 2024	41,625,512 shares
As of December 31, 2023	32,128,012 shares

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

As of December 31, 2024	286 shares
As of December 31, 2023	286 shares

(iii) Average number of shares during the period

Fiscal year ended December 31, 2024	35,118,450 shares
Fiscal year ended December 31, 2023	31,780,063 shares

(Reference) Summary of non-consolidated financial results

1. Non-consolidated financial results for the fiscal year ended December 31, 2024 (from January 1, 2024 to December 31, 2024)

(1) Non-consolidated operating results

(Percentages indicate year-on-year changes.)

	Net sales		Operating profit		Ordinary profit		Profit	
Fiscal year ended	Millions of yen	%	Millions of yen	%	Millions of yen	%	Millions of yen	%
December 31, 2024	469	9.8	(1,167)	–	(1,178)	–	(1,339)	–
December 31, 2023	427	4.0	(735)	–	(728)	–	(853)	–

	Earnings per share	Diluted earnings per share
Fiscal year ended	Yen	Yen
December 31, 2024	(38.15)	–
December 31, 2023	(26.85)	–

(2) Non-Consolidated financial position

	Total assets	Net assets	Equity ratio	Net assets per share
As of	Millions of yen	Millions of yen	%	Yen
December 31, 2024	1,615	686	42.4	16.45
December 31, 2023	2,371	1,281	54.0	39.88

Reference: Equity

As of December 31, 2024 ¥684 million

As of December 31, 2023 ¥1,281 million

2. Forecast of non-consolidated financial results for the fiscal year ending December 31, 2025 (from January 1, 2025 to December 31, 2025)

(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	(14.9)	(590)	–	(590)	–	(13.78)

* 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.

Attached Material

Index

1. Overview of operating results and others 2
(1) Overview of operating results for the fiscal year 2
(2) Overview of financial position for the fiscal year 5
(3) Overview of cash flows for the fiscal year 6
(4) Future outlook 6
(5) Significant events regarding premise of going concern 7
2. Basic rationale for selection of accounting standards 7
3. Consolidated financial statements and significant notes thereto 8
(1) Consolidated balance sheets 8
(2) Consolidated statements of income and consolidated statements of comprehensive income 10
Consolidated statements of income 10
Consolidated statements of comprehensive income 11
(3) Consolidated statements of changes in equity 12
(4) Consolidated statements of cash flows 14
(5) Notes to consolidated financial statements 15
(Notes on premise of going concern) 15
(Notes on segment information) 15
(Per share information) 17
(Subsequent events) 17
4. Non-consolidated financial statements and significant notes thereto 18
(1) Non-consolidated balance sheets 18
(2) Non-consolidated statements of income 20
(3) Non-consolidated statements of changes in equity 21

1. Overview of operating results and others

(1) Overview of operating results for the fiscal year

During the fiscal year ended December 31, 2024, 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 (ophthalmic surgical adjuvant DW-1002, both as single agent and combination drug, GLANATEC® ophthalmic solution 0.4% ("GLANATEC") for glaucoma treatment, GLA-ALPHA® combination ophthalmic solution for glaucoma treatment) recorded steady sales by licensees. DW-1002 in particular posted a substantial increase in revenue due to higher sales volume and the impact of the weaker yen.

Regarding the development pipeline, we completed the administration of internally developed H-1337 for glaucoma treatment to the subjects in Phase IIb clinical trials in the U.S. in August, and announced top-line data results in November. The trial results were favorable in having confirmed efficacy with no critical adverse events related to safety having been observed. As such, we are preparing for Phase III clinical trials and proceeding with out-licensing activities. We reapplied for DW-5LBT, which is a jointly developed neuropathic pain treatment in January and received a complete response letter in July. We are currently advancing an appropriate response to the matters identified by the FDA. Regarding regenerative cell therapy product DWR-2206, we began domestic Phase II clinical trials in March, and the transplant for the first subject was performed in July. As we obtained the necessary safety evaluation for continuing the clinical trials for the second subject and other subjects thereafter through subsequent follow-up observations, we further proceeded with the trials and completed all transplantation surgeries performed on subjects scheduled in December. Currently, we are evaluating and monitoring the data from the trials. In addition, we promoted the development of a product that had already been out-licensed.

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

As a result of the above, we have achieved steady progress with respect to each development pipeline with net sales having surpassed both previous fiscal year results and our initial earnings forecasts in the fiscal year ended December 31, 2024.

Royalty income, etc. from products on the market drove net sales of ¥471 million (up 10.1% year on year), while cost of sales came to ¥46 million (up 27.8% year on year). For GLANATEC, the period for receiving royalty income in Japan ended in September.

Selling, general and administrative expenses were ¥1,634 million (up 37.3% year on year). The breakdown of selling, general and administrative expenses was research and development expenses of ¥1,367 million (up 47.0% year on year), associated with increased development expenses of H-1337 and DWR-2206, and other selling, general and administrative expenses of ¥266 million (up 2.6% year on year).

This resulted in operating loss of ¥1,209 million (compared to operating loss of ¥798 million in the same period of the previous fiscal year). Ordinary loss came to ¥1,228 million (compared to ordinary loss of ¥796 million in the same period of the previous fiscal year) due to factors such as the recording of share issuance costs of ¥8 million in non-operating expenses. Loss attributable to owners of parent came to ¥1,290 million (compared to loss attributable to owners of parent of ¥812 million in the same period of the previous fiscal year) due to factors such as the recording of loss on redemption of convertible bonds of ¥60 million in extraordinary losses.

The state of new drug candidate compound development in the fiscal year ended December 31, 2024 was as follows.

(i) Product on market

Product name, etc.			Clinical indication	Region	Licensee
DW-1002	Brilliant Blue G	ILM-Blue®, TissueBlue™	ILM staining	Europe, U.S., etc.	DORC
	Brilliant Blue G/trypan blue	MembraneBlue-Dual®	ILM, ERM and PVR membrane staining	Europe, etc.	
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	

Note: For Japan, the period for receiving royalty income ended in September. For Asia, royalty income is received in certain areas.

(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	Phase II clinical trials	Japan	Jointly developed with ActualEyes

(A) 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 dying 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 staining and ERM staining 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.

(B) 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. For Japan, the period for receiving royalty income ended in September 2024.

(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. Moreover, Kowa has moved ahead with overseas expansion, and the product has been approved in certain areas of Asia. 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.

(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.

(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 subsequently began administering H-1337 in Phase IIb clinical trials in the U.S. in August 2023, and completed administration of this product in August 2024. The trial results were favorable in having confirmed efficacy of this product with no critical adverse events related to safety having been observed. As such, we are preparing for Phase III clinical trials and proceeding with out-licensing activities.

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 U.S. FDA (the U.S. Food and Drug Administration) and received a complete response letter. Having subsequently engaged in successive efforts involving reapplication and addressing of matters identified by the FDA, we are currently addressing the complete response letter received in July 2024 with the intention of reapplying.

(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 Inc. has been proceeding with development, and we began joint development with them in 2022. This is our first regenerative treatment with respect to which we began domestic Phase II clinical trials in Japan in March 2024 and completed all transplantation surgeries performed on subjects scheduled for December. Currently, we are evaluating and monitoring the data from the trials.

(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 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 addition, in terms of joint development with universities, etc., we are expanding indications of our internally developed products and actively moving forward with multiple projects targeting ophthalmic conditions.

(2) Overview of financial position for the fiscal year

Total assets decreased by ¥703 million from the end of the previous fiscal year to ¥1,669 million. Current assets decreased by ¥662 million from the end of the previous fiscal year to ¥1,475 million. The main factors were a decrease of ¥741 million in cash and deposits and other factors, despite an increase of ¥56 million in other under current assets. Non-current assets decreased by ¥41 million from the end of the previous fiscal year to ¥194 million. The main factors were a decrease of ¥41 million in contract-related intangible assets and other factors.

Liabilities decreased by ¥158 million from the end of the previous fiscal year to ¥935 million. Current liabilities decreased by ¥61 million from the end of the previous fiscal year to ¥132 million. The main factors were a decrease of ¥76 million in accounts payable - other and other factors, despite an increase of ¥9 million in current portion of long-term borrowings. Non-current liabilities decreased by ¥96 million from the end of the previous fiscal year to ¥802 million. The factors were increases of ¥302 million in bonds payable and ¥206 million in long-term borrowings, despite a decrease of ¥606 million in convertible-bond-type bonds with share acquisition rights.

Net assets decreased by ¥545 million from the end of the previous fiscal year to ¥733 million. The main factors were a decrease in retained earnings of ¥1,290 million caused by the recording of loss attributable to owners of parent and other factors, despite increases of ¥371 million in share capital and ¥371 million in capital surplus, as a result of the exercise of share acquisition rights.

As a result, the equity ratio was 43.9%.

(3) Overview of cash flows for the fiscal year

Cash and cash equivalents ("cash") as of December 31, 2024 decreased by ¥741 million from December 31, 2023 to ¥1,126 million.

The status of cash flows and their factors during the fiscal year ended December 31, 2024 are as follows.

Cash flows from operating activities

Net cash used in operating activities amounted to ¥1,299 million (¥586 million used in the previous fiscal year). This was mainly due to loss before income taxes of ¥1,288 million.

Cash flows from investing activities

Net cash used in investing activities amounted to ¥10 million (¥15 million used in the previous fiscal year). This was mainly due to purchase of property, plant and equipment of ¥9 million.

Cash flows from financing activities

Net cash provided by financing activities amounted to ¥567 million (¥134 million provided in the previous fiscal year). This was mainly due to proceeds from issuance of shares resulting from exercise of share acquisition rights of ¥710 million, proceeds from issuance of bonds of ¥660 million and proceeds from long-term borrowings of ¥226 million, despite redemption of convertible bonds of ¥666 million and redemption of bonds of ¥357 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 ¥471 million in the fiscal year ended December 31, 2024).

We forecast research and development expenses of ¥760 million (compared to research and development expenses of ¥1,367 million in the fiscal year ended December 31, 2024), which is attributable to factors that include costs of preparing for Phase III clinical trials of H-1337 in the U.S. and milestone payments associated with obtaining approval for DW-5LBT, in addition to usual research and development activities aimed at discovering new drug candidates.

As a result, we forecast operating loss of ¥670 million (compared to operating loss of ¥1,209 million in the fiscal year ended December 31, 2024), ordinary loss of ¥680 million (compared to ordinary loss of ¥1,228 million in the fiscal year ended December 31, 2024), and loss attributable to owners of parent of ¥680 million (compared to loss attributable to owners of parent of ¥1,290 million in the fiscal year ended December 31, 2024).

(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, the Company's cash and deposits stood at ¥1,126 million at the end of the current fiscal year, which is 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 that includes borrowings from main financial institutions along with share acquisition rights and bonds issued by means of third-party allotment.

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, 2023	As of December 31, 2024
Assets		
Current assets		
Cash and deposits	1,867,264	1,126,035
Accounts receivable - trade	117,144	125,023
Supplies	87,863	101,961
Other	65,687	122,361
Total current assets	2,137,959	1,475,382
Non-current assets		
Property, plant and equipment		
Buildings	8,727	8,727
Accumulated depreciation	(5,210)	(5,453)
Buildings, net	3,516	3,274
Tools, furniture and fixtures	102,666	109,498
Accumulated depreciation	(96,172)	(101,580)
Tools, furniture and fixtures, net	6,493	7,917
Total property, plant and equipment	10,010	11,192
Intangible assets		
Contract-related intangible assets	82,285	41,142
Other	4,224	3,290
Total intangible assets	86,510	44,432
Investments and other assets		
Investment securities	141,501	142,806
Other	8,690	8,236
Allowance for doubtful accounts	(11,301)	(12,606)
Total investments and other assets	138,890	138,436
Total non-current assets	235,411	194,061
Total assets	2,373,371	1,669,444
Liabilities		
Current liabilities		
Current portion of long-term borrowings	9,524	19,048
Accounts payable - other	161,362	84,904
Income taxes payable	11,708	14,876
Other	11,412	13,818
Total current liabilities	194,008	132,646
Non-current liabilities		
Long-term borrowings	269,476	476,428
Bonds payable	–	302,500
Convertible-bond-type bonds with share acquisition rights	606,122	–
Other	24,000	24,000
Total non-current liabilities	899,598	802,928
Total liabilities	1,093,606	935,574

(Thousands of yen)

	As of December 31, 2023	As of December 31, 2024
Net assets		
Shareholders' equity		
Share capital	831,617	1,203,277
Capital surplus	2,889,857	3,261,516
Retained earnings	(2,442,372)	(3,732,678)
Treasury shares	(0)	(0)
Total shareholders' equity	1,279,101	732,115
Accumulated other comprehensive income		
Valuation difference on available-for-sale securities	(36)	(34)
Total accumulated other comprehensive income	(36)	(34)
Share acquisition rights	699	1,788
Total net assets	1,279,764	733,869
Total liabilities and net assets	2,373,371	1,669,444

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

Consolidated statements of income

(Thousands of yen)

	Fiscal year ended December 31, 2023	Fiscal year ended December 31, 2024
Net sales	428,364	471,580
Cost of sales	36,666	46,843
Gross profit	391,697	424,736
Selling, general and administrative expenses		
Research and development expenses	930,506	1,367,769
Other	259,749	266,565
Total selling, general and administrative expenses	1,190,256	1,634,335
Operating loss	(798,558)	(1,209,598)
Non-operating income		
Interest income	10	76
Foreign exchange gains	6,713	1,637
Consumption tax difference	0	345
Other	11	14
Total non-operating income	6,735	2,073
Non-operating expenses		
Interest expenses	2,490	5,210
Share issuance costs	1,396	2,468
Share issuance costs	–	8,686
Loss on disposal of supplies	–	2,748
Other	653	1,458
Total non-operating expenses	4,540	20,571
Ordinary loss	(796,363)	(1,228,097)
Extraordinary losses		
Loss on valuation of investment securities	12,992	–
Provision of allowance for doubtful accounts	11,301	–
Impairment losses	6,146	–
Loss on redemption of convertible bonds	–	60,612
Total extraordinary losses	30,439	60,612
Loss before income taxes	(826,803)	(1,288,709)
Income taxes - current	1,595	1,595
Total income taxes	1,595	1,595
Loss	(828,398)	(1,290,305)
Loss attributable to non-controlling interests	(15,987)	–
Loss attributable to owners of parent	(812,411)	(1,290,305)

Consolidated statements of comprehensive income

(Thousands of yen)

	Fiscal year ended December 31, 2023	Fiscal year ended December 31, 2024
Loss	(828,398)	(1,290,305)
Other comprehensive income		
Valuation difference on available-for-sale securities	185	1
Total other comprehensive income	185	1
Comprehensive income	(828,212)	(1,290,303)
Comprehensive income attributable to		
Comprehensive income attributable to owners of parent	(812,225)	(1,290,303)
Comprehensive income attributable to non-controlling interests	(15,987)	–

(3) Consolidated statements of changes in equity

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

Fiscal year ended December 31, 2024

(Thousands of yen)

	Shareholders' equity				
	Share capital	Capital surplus	Retained earnings	Treasury shares	Total shareholders' equity
Balance at beginning of period	831,617	2,889,857	(2,442,372)	(0)	1,279,101
Changes during period					
Issuance of new shares	371,659	371,659			743,319
Loss attributable to owners of parent			(1,290,305)		(1,290,305)
Net changes in items other than shareholders' equity					
Total changes during period	371,659	371,659	(1,290,305)	–	(546,986)
Balance at end of period	1,203,277	3,261,516	(3,732,678)	(0)	732,115

	Accumulated other comprehensive income		Share acquisition rights	Total net assets
	Valuation difference on available-for-sale securities	Total accumulated other comprehensive income		
Balance at beginning of period	(36)	(36)	699	1,279,764
Changes during period				
Issuance of new shares				743,319
Loss attributable to owners of parent				(1,290,305)
Net changes in items other than shareholders' equity	1	1	1,089	1,090
Total changes during period	1	1	1,089	(545,895)
Balance at end of period	(34)	(34)	1,788	733,869

(4) Consolidated statements of cash flows

(Thousands of yen)

	Fiscal year ended December 31, 2023	Fiscal year ended December 31, 2024
Cash flows from operating activities		
Loss before income taxes	(826,803)	(1,288,709)
Depreciation	48,721	49,329
Impairment losses	6,146	–
Increase (decrease) in allowance for doubtful accounts	11,301	1,305
Share-based payment expenses	15,569	17,003
Loss on redemption of convertible bonds	–	60,612
Interest income	(10)	(76)
Interest expenses	2,490	5,210
Commission expenses	483	152
Foreign exchange losses (gains)	(961)	(1,570)
Share issuance costs	1,396	2,468
Share issuance costs	–	8,686
Loss (gain) on valuation of investment securities	12,992	–
Decrease (increase) in trade receivables	53,610	(7,879)
Decrease (increase) in inventories	22,594	(14,098)
Increase (decrease) in accounts payable - other	95,242	(74,766)
Other, net	(25,855)	(50,059)
Subtotal	(583,081)	(1,292,392)
Interest and dividends received	10	76
Interest paid	(2,158)	(5,197)
Income taxes paid	(1,593)	(1,605)
Net cash provided by (used in) operating activities	(586,821)	(1,299,118)
Cash flows from investing activities		
Purchase of property, plant and equipment	(12,026)	(9,025)
Purchase of intangible assets	(2,912)	(1,100)
Decrease (increase) in guarantee deposits	(316)	120
Net cash provided by (used in) investing activities	(15,254)	(10,005)
Cash flows from financing activities		
Proceeds from long-term borrowings	166,000	226,000
Repayments of long-term borrowings	(120,000)	(9,524)
Proceeds from issuance of bonds	–	660,000
Redemption of bonds	–	(357,500)
Redemption of convertible bonds	–	(666,734)
Proceeds from issuance of share acquisition rights	–	6,370
Proceeds from issuance of shares resulting from exercise of share acquisition rights	88,994	710,030
Purchase of treasury shares	(0)	–
Purchase of treasury share acquisition rights	–	(699)
Commission expenses paid	(527)	(313)
Net cash provided by (used in) financing activities	134,466	567,628
Effect of exchange rate change on cash and cash equivalents	205	266
Net increase (decrease) in cash and cash equivalents	(467,404)	(741,229)
Cash and cash equivalents at beginning of period	2,334,668	1,867,264
Cash and cash equivalents at end of period	1,867,264	1,126,035

(5) Notes to consolidated financial statements

(Notes on premise of going concern)

Not applicable.

(Notes on segment information)

(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, 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.

Fiscal year ended December 31, 2024 (from January 1, 2024 to December 31, 2024)

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
335,476	136,097	5	471,580

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.	335,476
Kowa Company, Ltd.	126,036

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, 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.

Fiscal year ended December 31, 2024 (from January 1, 2024 to December 31, 2024)

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, 2023 (from January 1, 2023 to December 31, 2023)	Fiscal year ended December 31, 2024 (from January 1, 2024 to December 31, 2024)
Net assets per share	39.81	17.59
Loss per share	(25.56)	(36.74)

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, 2023 (from January 1, 2023 to December 31, 2023)	Fiscal year ended December 31, 2024 (from January 1, 2024 to December 31, 2024)
Loss attributable to owners of parent (Thousands of yen)	(812,411)	(1,290,305)
Value not attributable to shareholders of common shares (Thousands of yen)	–	–
Loss attributable to owners of parent related to common shares (Thousands of yen)	(812,411)	(1,290,305)
Average number of shares outstanding during the period (Shares)	31,780,063	35,118,450
Overview of potential shares not included in the calculation of the diluted earnings per share because of the lack of dilution effects	1st series unsecured convertible bonds with share acquisition rights Number of share acquisition rights: 33 units (Common shares: 3,276,352 shares) 11th series of share acquisition rights Number of share acquisition rights: 13,990 units (Common shares: 1,399,000 shares)	12th series of share acquisition rights Number of share acquisition rights: 36,500 units (Common shares: 3,650,000 shares)

(Subsequent events)

Issuance of new shares due to the exercise of share acquisition rights

Part of the 12th series of share acquisition rights (with an exercise price adjustment clause) issued by the Company through third-party allotment on June 3, 2024 have been exercised in the period from January 1, 2025 to February 7, 2025 as follows. Regarding the 12th series of share acquisition rights (with an exercise price adjustment clause), the exercise of all share acquisition rights has been completed on February 7, 2025.

12th series of share acquisition rights

1. Number of units of share acquisition rights exercised: 36,500 units
2. Type and number of shares issued: Common shares: 3,650,000 shares
3. Increase in share capital: ¥209,744 thousand
4. Increase in legal capital surplus: ¥209,744 thousand

4. Non-consolidated financial statements and significant notes thereto

(1) Non-consolidated balance sheets

(Thousands of yen)

	As of December 31, 2023	As of December 31, 2024
Assets		
Current assets		
Cash and deposits	1,754,446	1,072,785
Accounts receivable - trade	117,144	124,941
Supplies	85,107	101,953
Advance payments to suppliers	33,292	35,667
Prepaid expenses	17,269	21,439
Short-term loans receivable from subsidiaries and associates	100,000	100,000
Other	29,087	64,605
Allowance for doubtful accounts	–	(100,000)
Total current assets	2,136,347	1,421,393
Non-current assets		
Property, plant and equipment		
Buildings	3,516	3,274
Tools, furniture and fixtures	6,493	7,917
Total property, plant and equipment	10,010	11,192
Intangible assets		
Software	4,151	3,217
Contract-related intangible assets	82,285	41,142
Other	72	72
Total intangible assets	86,510	44,432
Investments and other assets		
Investment securities	141,501	142,806
Shares of subsidiaries and associates	0	0
Other	8,690	8,236
Allowance for doubtful accounts	(11,301)	(12,606)
Total investments and other assets	138,890	138,436
Total non-current assets	235,411	194,061
Total assets	2,371,758	1,615,455
Liabilities		
Current liabilities		
Current portion of long-term borrowings	9,524	19,048
Accounts payable - other	161,034	84,533
Accrued expenses	5,786	4,591
Income taxes payable	11,090	14,257
Deposits received	2,828	3,647
Total current liabilities	190,263	126,077
Non-current liabilities		
Long-term borrowings	269,476	476,428
Bonds payable	–	302,500
Convertible-bond-type bonds with share acquisition rights	606,122	–
Other	24,000	24,000
Total non-current liabilities	899,598	802,928
Total liabilities	1,089,862	929,005

(Thousands of yen)

	As of December 31, 2023	As of December 31, 2024
Net assets		
Shareholders' equity		
Share capital	831,617	1,203,277
Capital surplus		
Legal capital surplus	2,930,959	3,302,619
Total capital surplus	2,930,959	3,302,619
Retained earnings		
Other retained earnings		
Retained earnings brought forward	(2,481,343)	(3,821,200)
Total retained earnings	(2,481,343)	(3,821,200)
Treasury shares	(0)	(0)
Total shareholders' equity	1,281,233	684,695
Valuation and translation adjustments		
Valuation difference on available-for-sale securities	(36)	(34)
Total valuation and translation adjustments	(36)	(34)
Share acquisition rights	699	1,788
Total net assets	1,281,896	686,449
Total liabilities and net assets	2,371,758	1,615,455

(2) Non-consolidated statements of income

(Thousands of yen)

	Fiscal year ended December 31, 2023	Fiscal year ended December 31, 2024
Net sales	427,968	469,923
Cost of sales	36,666	46,843
Gross profit	391,301	423,080
Selling, general and administrative expenses		
Research and development expenses	895,142	1,351,067
Other	231,645	239,118
Total selling, general and administrative expenses	1,126,787	1,590,185
Operating loss	(735,486)	(1,167,105)
Non-operating income		
Interest income	1,009	1,070
Foreign exchange gains	6,713	1,637
Commission income	3,600	3,600
Other	5	352
Total non-operating income	11,328	6,660
Non-operating expenses		
Interest expenses	2,490	5,210
Share issuance costs	1,396	2,468
Share issuance costs	–	8,686
Other	610	1,458
Total non-operating expenses	4,497	17,823
Ordinary loss	(728,655)	(1,178,267)
Extraordinary losses		
Loss on valuation of investment securities	12,992	–
Provision of allowance for doubtful accounts	11,301	100,000
Loss on redemption of convertible bonds	–	60,612
Loss on valuation of shares of subsidiaries and associates	99,278	–
Total extraordinary losses	123,572	160,612
Loss before income taxes	(852,228)	(1,338,880)
Income taxes - current	977	977
Total income taxes	977	977
Loss	(853,205)	(1,339,857)

(3) Non-consolidated statements of changes in equity

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	Total retained earnings		
				Retained earnings brought forward			
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

Fiscal year ended December 31, 2024

(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	Total retained earnings		
				Retained earnings brought forward			
Balance at beginning of period	831,617	2,930,959	2,930,959	(2,481,343)	(2,481,343)	(0)	1,281,233
Changes during period							
Issuance of new shares	371,659	371,659	371,659				743,319
Loss				(1,339,857)	(1,339,857)		(1,339,857)
Net changes in items other than shareholders' equity							
Total changes during period	371,659	371,659	371,659	(1,339,857)	(1,339,857)	–	(596,538)
Balance at end of period	1,203,277	3,302,619	3,302,619	(3,821,200)	(3,821,200)	(0)	684,695

	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	(36)	(36)	699	1,281,896
Changes during period				
Issuance of new shares				743,319
Loss				(1,339,857)
Net changes in items other than shareholders' equity	1	1	1,089	1,090
Total changes during period	1	1	1,089	(595,447)
Balance at end of period	(34)	(34)	1,788	686,449