

Translation

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November 14, 2024

Consolidated Financial Results for the Nine Months Ended September 30, 2024 (Based on Japanese GAAP)

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Securities code: 4576
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Scheduled date to commence dividend payments: —
Preparation of supplementary material on financial results: No
Holding of financial results meeting: No

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

1. Consolidated financial results for the nine months ended September 30, 2024 (from January 1, 2024 to September 30, 2024)

(1) Consolidated operating results (cumulative)

(Percentages indicate year-on-year changes.)

	Net sales		Operating profit		Ordinary profit		Profit attributable to owners of parent	
	Millions of yen	%	Millions of yen	%	Millions of yen	%	Millions of yen	%
Nine months ended								
September 30, 2024	348	11.1	(647)	—	(665)	—	(727)	—
September 30, 2023	313	1.6	(457)	—	(453)	—	(443)	—

Note: Comprehensive income For the nine months ended September 30, 2024 ¥(727) million [—%]
For the nine months ended September 30, 2023 ¥(455) million [—%]

	Earnings per share	Diluted earnings per share
Nine months ended	Yen	Yen
September 30, 2024	(21.61)	—
September 30, 2023	(14.02)	—

(2) Consolidated financial position

	Total assets	Net assets	Equity ratio
As of	Millions of yen	Millions of yen	%
September 30, 2024	2,191	1,019	46.4
December 31, 2023	2,373	1,279	53.9

Reference: Equity

As of September 30, 2024 ¥1,016 million

As of December 31, 2023 ¥1,279 million

2. Cash dividends

	Annual dividends per share				
	1st quarter-end	2nd quarter-end	3rd quarter-end	Fiscal year-end	Total
	Yen	Yen	Yen	Yen	Yen
Fiscal year ended December 31, 2023	—	0.00	—	0.00	0.00
Fiscal year ending December 31, 2024	—	0.00	—		
Fiscal year ending December 31, 2024 (Forecast)				0.00	0.00

Note: Revisions to the dividend forecast most recently announced: None

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)

Note: Revisions to the forecast of consolidated financial results most recently announced: None

*** Notes**

(1) Significant changes in the scope of consolidation during the nine months ended September 30, 2024:
No

(2) Application of special accounting methods for preparing quarterly consolidated financial statements:
No

(3) 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

(4) Number of issued shares (common shares)

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

As of September 30, 2024	37,975,512 shares
As of December 31, 2023	32,128,012 shares

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

As of September 30, 2024	286 shares
As of December 31, 2023	286 shares

(iii) Average number of shares during the period

Nine months ended September 30, 2024	33,645,372 shares
Nine months ended September 30, 2023	31,662,901 shares

* Review of the Japanese-language originals of the attached quarterly consolidated financial statements by certified public accountants or an audit corporation: No

* Proper use of earnings forecasts, and other special matters
(Caution regarding forward-looking statements and others)

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 “(3) Explanation of the consolidated forecasts and other forward-looking forecasted information” of “1. Overview of operating results and others” on page 4 of the attached materials.

Attached Material

Index

1. Overview of operating results and others	2
(1) Overview of operating results for the nine months ended September 30, 2024	2
(2) Overview of financial position for the nine months ended September 30, 2024.....	4
(3) Explanation of the consolidated forecasts and other forward-looking forecasted information	4
(4) Significant events regarding premise of going concern	4
2. Quarterly consolidated financial statements and significant notes thereto	5
(1) Quarterly consolidated balance sheets.....	5
(2) Quarterly consolidated statements of income and consolidated statements of comprehensive income	6
Quarterly consolidated statements of income (cumulative)	6
Quarterly consolidated statements of comprehensive income (cumulative)	7
(3) Notes to quarterly consolidated financial statements	8
(Notes on segment information).....	8
(Notes concerning significant changes in shareholders' equity (if any)).....	8
(Notes on premise of going concern)	8
(Notes on quarterly consolidated statements of cash flows)	8
(Subsequent events).....	8

1. Overview of operating results and others

(1) Overview of operating results for the nine months ended September 30, 2024

During the first nine months of the fiscal year ending 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.

Regarding the development pipeline, 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 submitted a notification of clinical trial plan for domestic Phase II clinical trials to the Pharmaceuticals and Medical Devices Agency (PMDA) 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 will continue the evaluations of the trials. 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. Currently, we are analyzing 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 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, royalty income, etc. from products on the market drove net sales of ¥348 million (up 11.1% year on year), while cost of sales came to ¥33 million (up 22.2% year on year). For GLANATEC, the period for receiving royalty income in Japan ended in September.

Selling, general and administrative expenses were ¥962 million (up 29.4% year on year). The breakdown of selling, general and administrative expenses was research and development expenses of ¥767 million (up 40.7% year on year), associated with increased development expenses of H-1337 and DWR-2206, and other selling, general and administrative expenses of ¥195 million (down 1.6% year on year).

This resulted in operating loss of ¥647 million (compared to operating loss of ¥457 million in the same period of the previous fiscal year). Ordinary loss came to ¥665 million (compared to ordinary loss of ¥453 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 ¥727 million (compared to loss attributable to owners of parent of ¥443 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 first nine months of the fiscal year ending 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

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

(2) Overview of financial position for the nine months ended September 30, 2024

Total assets decreased by ¥181 million from the end of the previous fiscal year to ¥2,191 million. Current assets decreased by ¥152 million from the end of the previous fiscal year to ¥1,985 million. The main factors were a decrease of ¥706 million in cash and deposits, despite increases of ¥490 million in advance payments to suppliers and ¥48 million in accounts receivable - trade. Non-current assets decreased by ¥28 million from the end of the previous fiscal year to ¥206 million. The main factor was a decrease of ¥30 million in contract-related intangible assets.

Liabilities increased by ¥78 million from the end of the previous fiscal year to ¥1,172 million. Current liabilities decreased by ¥86 million from the end of the previous fiscal year to ¥107 million. The main factors were an increase of ¥9 million in current portion of long-term borrowings, despite a decrease of ¥94 million in accounts payable - others. Non-current liabilities increased by ¥165 million from the end of the previous fiscal year to ¥1,064 million. The main factors were increases of ¥577 million in bonds payable and ¥193 million in long-term borrowings, despite a decrease of ¥606 million in convertible-bond-type bonds with share acquisition rights.

Net assets decreased by ¥260 million from the end of the previous fiscal year to ¥1,019 million. The main factors were a decrease in retained earnings of ¥727 million caused by the recording of loss attributable to owners of parent and other factors, despite increases of ¥232 million in share capital and ¥232 million in capital surplus, as a result of the exercise of share acquisition rights.

As a result, the equity ratio was 46.4%.

(3) Explanation of the consolidated forecasts and other forward-looking forecasted information

Regarding the full-year consolidated forecasts for the fiscal year ending December 31, 2024, there is no change in the earnings forecasts announced on February 9, 2024.

(4) 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.

On the cash front, as of September 30, 2024, the Company's cash and deposits stood at ¥1,160 million, sufficient cash to fund the present 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. Quarterly consolidated financial statements and significant notes thereto

(1) Quarterly consolidated balance sheets

(Thousands of yen)

	As of December 31, 2023	As of September 30, 2024
Assets		
Current assets		
Cash and deposits	1,867,264	1,160,528
Accounts receivable - trade	117,144	165,247
Supplies	87,863	102,778
Advance payments to suppliers	17,192	507,737
Other	48,495	49,061
Total current assets	2,137,959	1,985,353
Non-current assets		
Property, plant and equipment	10,010	12,855
Intangible assets		
Contract-related intangible assets	82,285	51,428
Other	4,224	3,523
Total intangible assets	86,510	54,952
Investments and other assets		
Other	150,191	150,040
Allowance for doubtful accounts	(11,301)	(11,239)
Total investments and other assets	138,890	138,800
Total non-current assets	235,411	206,608
Total assets	2,373,371	2,191,961
Liabilities		
Current liabilities		
Current portion of long-term borrowings	9,524	19,048
Accounts payable - other	161,362	66,757
Income taxes payable	11,708	7,718
Other	11,412	14,144
Total current liabilities	194,008	107,667
Non-current liabilities		
Bonds payable	—	577,500
Convertible-bond-type bonds with share acquisition rights	606,122	—
Long-term borrowings	269,476	463,190
Other	24,000	24,000
Total non-current liabilities	899,598	1,064,690
Total liabilities	1,093,606	1,172,357
Net assets		
Shareholders' equity		
Share capital	831,617	1,063,750
Capital surplus	2,889,857	3,121,989
Retained earnings	(2,442,372)	(3,169,569)
Treasury shares	(0)	(0)
Total shareholders' equity	1,279,101	1,016,170
Accumulated other comprehensive income		
Valuation difference on available-for-sale securities	(36)	(144)
Total accumulated other comprehensive income	(36)	(144)
Share acquisition rights	699	3,577
Total net assets	1,279,764	1,019,603
Total liabilities and net assets	2,373,371	2,191,961

(2) Quarterly consolidated statements of income and consolidated statements of comprehensive income**Quarterly consolidated statements of income (cumulative)**

(Thousands of yen)

	Nine months ended September 30, 2023	Nine months ended September 30, 2024
Net sales	313,994	348,913
Cost of sales	27,730	33,885
Gross profit	286,264	315,028
Selling, general and administrative expenses		
Research and development expenses	545,612	767,463
Other	198,289	195,212
Total selling, general and administrative expenses	743,901	962,675
Operating loss	(457,637)	(647,647)
Non-operating income		
Interest income	10	76
Foreign exchange gains	7,394	–
Reversal of allowance for doubtful accounts	–	61
Other	11	14
Total non-operating income	7,416	152
Non-operating expenses		
Interest expenses	1,816	3,548
Share issuance costs	1,396	1,502
Commission expenses	376	140
Share issuance costs	–	8,686
Other	137	4,014
Total non-operating expenses	3,726	17,892
Ordinary loss	(453,947)	(665,387)
Extraordinary losses		
Loss on redemption of convertible bonds	–	60,612
Total extraordinary losses	–	60,612
Loss before income taxes	(453,947)	(725,999)
Income taxes - current	1,196	1,196
Total income taxes	1,196	1,196
Loss	(455,144)	(727,196)
Loss attributable to non-controlling interests	(11,223)	–
Loss attributable to owners of parent	(443,920)	(727,196)

Quarterly consolidated statements of comprehensive income (cumulative)

(Thousands of yen)

	Nine months ended September 30, 2023	Nine months ended September 30, 2024
Loss	(455,144)	(727,196)
Other comprehensive income		
Valuation difference on available-for-sale securities	73	(107)
Total other comprehensive income	73	(107)
Comprehensive income	(455,070)	(727,303)
Comprehensive income attributable to		
Comprehensive income attributable to owners of parent	(443,846)	(727,303)
Comprehensive income attributable to non-controlling interests	(11,223)	—

(3) Notes to quarterly consolidated financial statements**(Notes on segment information)**

[Segment information]

Nine months ended September 30, 2023

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

Nine months ended September 30, 2024

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

(Notes concerning significant changes in shareholders' equity (if any))

We exercised the 12th series of share acquisition rights in the first nine months of the fiscal year ending December 31, 2024. As a result, share capital and legal capital surplus respectively increased by ¥232,132 thousand, and as of September 30, 2024, share capital stood at ¥1,063,750 thousand and legal capital surplus stood at ¥3,121,989 thousand.

(Notes on premise of going concern)

Not applicable.

(Notes on quarterly consolidated statements of cash flows)

Quarterly consolidated statements of cash flows are not prepared for the nine months ended September 30, 2024. Depreciation (including amortization of intangible assets) for the nine-month period under review is as follows:

	Nine months ended September 30, 2023	Nine months ended September 30, 2024
Depreciation	¥35,738 thousand	¥36,813 thousand

(Subsequent events)

Not applicable.