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.

November 13, 2025

Consolidated Financial Results for the Nine Months Ended September 30, 2025 (Based on Japanese GAAP)

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Listing: Tokyo
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, 2025 (from January 1, 2025 to September 30, 2025)

(1) Consolidated operating results (cumulative)

(Percentages indicate year-on-year changes.)

	Net sales		Operating profit		Ordinary profit		Profit attributable to owners of parent	
Nine months ended	Millions of yen	%	Millions of yen	%	Millions of yen	%	Millions of yen	%
September 30, 2025	297	(14.9)	(478)	–	(491)	–	(492)	–
September 30, 2024	348	11.1	(647)	–	(665)	–	(727)	–

Note: Comprehensive income For the nine months ended September 30, 2025 ¥(492) million [–%]
For the nine months ended September 30, 2024 ¥(727) million [–%]

	Earnings per share	Diluted earnings per share
Nine months ended	Yen	Yen
September 30, 2025	(10.75)	–
September 30, 2024	(21.61)	–

(2) Consolidated financial position

	Total assets	Net assets	Equity ratio
As of	Millions of yen	Millions of yen	%
September 30, 2025	2,178	1,464	67.2
December 31, 2024	1,669	733	43.9

Reference: Equity
As of September 30, 2025 ¥1,463 million
As of December 31, 2024 ¥732 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, 2024	–	0.00	–	0.00	0.00
Fiscal year ending December 31, 2025	–	0.00	–		
Fiscal year ending December 31, 2025 (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, 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)

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, 2025: 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: Yes

(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, 2025	53,139,712 shares
As of December 31, 2024	41,625,512 shares

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

As of September 30, 2025	286 shares
As of December 31, 2024	286 shares

(iii) Average number of shares during the period

Nine months ended September 30, 2025	45,850,730 shares
Nine months ended September 30, 2024	33,645,372 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

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1. Overview of operating results and others

(1) Overview of operating results for the nine months ended September 30, 2025

During the first nine months of the fiscal year ending December 31, 2025, 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, GLA-ALPHA® combination ophthalmic solution for glaucoma treatment ("GLA-ALPHA"), etc.) recorded steady sales by licensees. GLA-ALPHA was launched in Thailand as the first overseas expansion in July.

Regarding our development pipeline, the out-licensed product DW-1002 was approved in China in February. In addition, Fuchs' endothelial corneal dystrophy treatment K-321 is undergoing two global Phase III clinical trials, and administration to subjects was completed in March and June, respectively, with follow-up observations currently underway. The jointly developed drug, DW-5LBT, which is a treatment for nerve pain, was resubmitted in March and approved in September. Currently, we are proceeding with preparations to put this drug on the market, including the selection of sales partners, and plan to start sales in the first half of 2026. Furthermore, we decided to proceed with the development of H-1129, which is a proprietary product, as a therapeutic agent for keratoconjunctival diseases based on immune disorders in July. The development plan will be announced once it has been finalized. Moreover, we also continued to develop each of the other products.

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 each product on the market drove net sales of ¥297 million (down 14.9% year on year), while cost of sales came to ¥30 million (down 11.3% year on year).

Selling, general and administrative expenses were ¥745 million (down 22.6% year on year). The breakdown of selling, general and administrative expenses was research and development expenses of ¥535 million (down 30.2% year on year, the US late-stage Phase II clinical trial of H-1337 was performed in the previous fiscal year), and other selling, general and administrative expenses of ¥210 million (up 7.6% year on year) due to an increase in personnel expenses, etc.

This resulted in operating loss of ¥478 million (compared to operating loss of ¥647 million in the same period of the previous fiscal year). Ordinary loss came to ¥491 million (compared to ordinary loss of ¥665 million in the same period of the previous fiscal year) due to factors such as the recording of interest expenses of ¥6 million and share issuance costs of ¥6 million in non-operating expenses. Loss attributable to owners of parent came to ¥492 million (compared to loss attributable to owners of parent of ¥727 million in the same period of the previous fiscal year).

The state of new drug candidate compound development in the first nine months of the fiscal year ending December 31, 2025 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/Brimonidine tartrate		GLA-ALPHA® combination ophthalmic solution	Glaucoma and ocular hypertension	Japan, Asia	Kowa

Note: We have received royalties for GLANATEC® ophthalmic solution 0.4% in some parts 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	Approval	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	Late Phase II clinical trials	U.S.	Developed internally
DW-5LBT		Neuropathic pain after shingles	Approval	U.S.	Jointly developed with MEDRx
DWR-2206		Bullous Keratopathy	Phase II clinical trials	Japan	Jointly developed with ActualEyes
H-1129		Therapeutic agent for keratoconjunctival diseases based on immune disorders (undisclosed)	In preparation for clinical trials	Japan	Developed internally

(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 indications 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, 2025

Total assets increased by ¥509 million from the end of the previous fiscal year to ¥2,178 million. Current assets increased by ¥542 million from the end of the previous fiscal year to ¥2,018 million. The main factor was an increase of ¥527 million in cash and deposits due to the exercise of 13th series of share acquisition rights and other factors. Non-current assets decreased by ¥33 million from the end of the previous fiscal year to ¥160 million. The main factors were a decrease of ¥30 million in contract-related intangible assets and other factors.

Liabilities decreased by ¥221 million from the end of the previous fiscal year to ¥714 million. Current liabilities increased by ¥87 million from the end of the previous fiscal year to ¥220 million. The main factors were an increase of ¥76 million in accounts payable - other due to milestone payments related to DW-5LBT and other factors, and an increase of ¥27 million in current portion of long-term borrowings. Non-current liabilities decreased by ¥309 million from the end of the previous fiscal year to ¥493 million. The main factor was a decrease of ¥302 million in bonds due to early redemption of the first series of unsecured bonds.

Net assets increased by ¥730 million from the end of the previous fiscal year to ¥1,464 million. The main factors were increases of ¥612 million in share capital and ¥612 million in capital surplus, as a result of the exercise of share acquisition rights and other factors, despite a decrease of ¥492 million in retained earnings caused by the recording of loss attributable to owners of parent. Pursuant to the resolution of the 27th Ordinary General Meeting of Shareholders, we transferred share capital of ¥1,173 million and legal capital surplus of ¥2,647 million to other capital surplus, and transferred the resulting other capital surplus of ¥3,821 million to retained earnings for the purpose of deficit disposition. However, this did not result in any change in total net assets.

As a result, the equity ratio was 67.2%.

(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, 2025, there is no change in the earnings forecasts announced on February 10, 2025.

(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, the Company’s cash and deposits stood at ¥1,654 million as of September 30, 2025, which is sufficient cash to fund the current 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 exercise of share acquisition rights through 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. Quarterly consolidated financial statements and significant notes thereto

(1) Quarterly consolidated balance sheets

(Thousands of yen)

	As of December 31, 2024	As of September 30, 2025
Assets		
Current assets		
Cash and deposits	1,126,035	1,654,031
Accounts receivable - trade	125,023	144,151
Supplies	101,961	102,386
Other	122,361	117,676
Total current assets	1,475,382	2,018,245
Non-current assets		
Property, plant and equipment	11,192	9,727
Intangible assets		
Contract-related intangible assets	41,142	10,285
Other	3,290	2,589
Total intangible assets	44,432	12,875
Investments and other assets		
Other	151,042	149,607
Allowance for doubtful accounts	(12,606)	(11,723)
Total investments and other assets	138,436	137,883
Total non-current assets	194,061	160,486
Total assets	1,669,444	2,178,731
Liabilities		
Current liabilities		
Current portion of long-term borrowings	19,048	46,548
Accounts payable - other	84,904	161,760
Income taxes payable	14,876	1,196
Other	13,818	10,968
Total current liabilities	132,646	220,473
Non-current liabilities		
Bonds payable	302,500	–
Long-term borrowings	476,428	469,642
Other	24,000	24,000
Total non-current liabilities	802,928	493,642
Total liabilities	935,574	714,115
Net assets		
Shareholders' equity		
Share capital	1,203,277	642,004
Capital surplus	3,261,516	1,225,597
Retained earnings	(3,732,678)	(404,193)
Treasury shares	(0)	(0)
Total shareholders' equity	732,115	1,463,407
Accumulated other comprehensive income		
Valuation difference on available-for-sale securities	(34)	(144)
Total accumulated other comprehensive income	(34)	(144)
Share acquisition rights	1,788	1,352
Total net assets	733,869	1,464,615
Total liabilities and net assets	1,669,444	2,178,731

(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, 2024	Nine months ended September 30, 2025
Net sales	348,913	297,097
Cost of sales	33,885	30,062
Gross profit	315,028	267,034
Selling, general and administrative expenses		
Research and development expenses	767,463	535,424
Other	195,212	210,061
Total selling, general and administrative expenses	962,675	745,485
Operating loss	(647,647)	(478,450)
Non-operating income		
Interest income	76	1,560
Foreign exchange gains	–	758
Reversal of allowance for doubtful accounts	61	883
Other	14	103
Total non-operating income	152	3,305
Non-operating expenses		
Interest expenses	3,548	6,078
Share issuance costs	1,502	3,255
Commission expenses	140	9
Share issuance costs	8,686	6,008
Other	4,014	1,022
Total non-operating expenses	17,892	16,374
Ordinary loss	(665,387)	(491,520)
Extraordinary losses		
Loss on redemption of convertible bonds	60,612	–
Total extraordinary losses	60,612	–
Loss before income taxes	(725,999)	(491,520)
Income taxes - current	1,196	1,196
Total income taxes	1,196	1,196
Loss	(727,196)	(492,716)
Loss attributable to owners of parent	(727,196)	(492,716)

Quarterly consolidated statements of comprehensive income (cumulative)

(Thousands of yen)

	Nine months ended September 30, 2024	Nine months ended September 30, 2025
Loss	(727,196)	(492,716)
Other comprehensive income		
Valuation difference on available-for-sale securities	(107)	(109)
Total other comprehensive income	(107)	(109)
Comprehensive income	(727,303)	(492,826)
Comprehensive income attributable to		
Comprehensive income attributable to owners of parent	(727,303)	(492,826)
Comprehensive income attributable to non-controlling interests	–	–

(3) Notes to quarterly consolidated financial statements

(Notes on changes in accounting policies)

(Application of the "Accounting Standard for Current Income Taxes," etc.)

The Group has applied the "Accounting Standard for Current Income Taxes" (Accounting Standards Board of Japan (ASBJ) Statement No. 27, October 28, 2022), "Accounting Standard for Presentation of Comprehensive Income" (ASBJ Statement No. 25, October 28, 2022) and "Guidance on Accounting Standard for Tax Effect Accounting" (ASBJ Guidance No. 28, October 28, 2022) from the beginning of the first three months of the fiscal year ending December 31, 2025. This has no impact on the quarterly consolidated financial statements.

(Notes on segment information)

(Segment information)

Nine months ended September 30, 2024

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

Nine months ended September 30, 2025

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))

Based on the resolution of the 27th Ordinary General Meeting of Shareholders held on March 25, 2025, the Company reduced the amounts of its share capital and legal capital surplus as of May 1, 2025, transferred the amounts to other capital surplus, and transferred the sum total amount of the increased other capital surplus to retained earnings brought forward for the purpose of deficit disposition.

As a result, share capital decreased by ¥1,173,277 thousand and legal capital surplus decreased by ¥2,647,923 thousand, and retained earnings brought forward increased by ¥3,821,200 thousand.

In addition, due to the payment from the exercise of the 12th series of share acquisition rights (with an exercise price adjustment clause), which were issued through a third-party allotment on June 3, 2024, and from the exercise of the 13th series of share acquisition rights (with an exercise price adjustment clause), which were issued through a third-party allotment on July 31, 2025, share capital and legal capital surplus each increased by ¥587,073 thousand.

Furthermore, the issuance of new shares as restricted stock unit with a payment date of May 13, 2025, resulted in an additional increase of ¥24,931 thousand in both share capital and legal capital surplus.

As a result, as of September 30, 2025, share capital stood at ¥642,004 thousand, legal capital surplus at ¥1,225,597 thousand, and retained earnings brought forward at a deficit of ¥404,193 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, 2025. Depreciation (including amortization of intangible assets) for the nine-month period under review is as follows:

	Nine months ended September 30, 2024	Nine months ended September 30, 2025
Depreciation	¥36,813 thousand	¥35,550 thousand

(Subsequent events)

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

Part of the 13th series of share acquisition rights (with an exercise price adjustment clause) issued by the Company through third-party allotment on July 31, 2025 have been exercised in the period from October 1, 2025 to November 12, 2025 as follows.

13th series of share acquisition rights

1. Number of units of share acquisition rights exercised	10,720 units
2. Class and number of shares issued	Common shares: 1,072,000 shares
3. Increase in share capital	¥53,541 thousand
4. Increase in legal capital surplus	¥53,541 thousand