

Translation

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August 9, 2024

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

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Listing: Tokyo
Securities code: 4576
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Scheduled date to file semi-annual securities report: August 9, 2024
Scheduled date to commence dividend payments: –
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 six months ended June 30, 2024 (from January 1, 2024 to June 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	%
Six months ended								
June 30, 2024	223	19.1	(449)	–	(459)	–	(520)	–
June 30, 2023	187	(10.6)	(258)	–	(254)	–	(247)	–

Note: Comprehensive income For the six months ended June 30, 2024 ¥(520) million [–%]
For the six months ended June 30, 2023 ¥(255) million [–%]

	Earnings per share	Diluted earnings per share
Six months ended	Yen	Yen
June 30, 2024	(16.15)	–
June 30, 2023	(7.89)	–

(2) Consolidated financial position

	Total assets	Net assets	Equity ratio
As of	Millions of yen	Millions of yen	%
June 30, 2024	2,065	856	41.2
December 31, 2023	2,373	1,279	53.9

Reference: Equity

As of June 30, 2024 ¥850 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 six months ended June 30, 2024: No
- (2) Application of special accounting methods for preparing semi-annual 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 June 30, 2024	33,175,512 shares
As of December 31, 2023	32,128,012 shares

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

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

- (iii) Average number of shares during the period

Six months ended June 30, 2024	32,239,072 shares
Six months ended June 30, 2023	31,448,528 shares

* Semi-annual financial results reports are exempt from review conducted by certified public accountants or an audit corporation.

* 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. Qualitative information regarding financial results for the first six months of the fiscal year ending December 31, 2024" on page 4 of the attached materials.

(Supplementary material on financial results)

Supplementary material on financial results are scheduled to be disclosed via TDnet on the same day.

Attached Material

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1. Qualitative information regarding financial results for the first six months of the fiscal year ending December 31, 2024

(1) Explanation of operating results

During the first six 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% 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 are moving forward with preparations such as selection of subjects. In addition, we promoted the development of a product that had already been out-licensed and an internally developed product, respectively.

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 ¥223 million (up 19.1% year on year), while cost of sales came to ¥18 million (up 26.1% year on year).

Selling, general and administrative expenses were ¥654 million (up 51.8% year on year). The breakdown of selling, general and administrative expenses was research and development expenses of ¥521 million (up 76.9% year on year), associated with increased development expenses of H-1337 and DWR-2206, and other selling, general and administrative expenses of ¥133 million (down 2.3% year on year).

This resulted in operating loss of ¥449 million (compared to operating loss of ¥258 million in the same period of the previous fiscal year). Ordinary loss came to ¥459 million (compared to ordinary loss of ¥254 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 ¥520 million (compared to loss attributable to owners of parent of ¥247 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 six 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: 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	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) Explanation of financial position

(i) Assets, liabilities and net assets

Total assets decreased by ¥307 million from the end of the previous fiscal year to ¥2,065 million. Current assets decreased by ¥290 million from the end of the previous fiscal year to ¥1,847 million. The main factors were a decrease of ¥566 million in cash and deposits, despite increases of ¥260 million in advance payments to suppliers and ¥15 million in supplies. Non-current assets decreased by ¥17 million from the end of the previous fiscal year to ¥217 million. The main factor was a decrease of ¥20 million in contract-related intangible assets.

Liabilities increased by ¥115 million from the end of the previous fiscal year to ¥1,209 million. Current liabilities decreased by ¥98 million from the end of the previous fiscal year to ¥95 million. The main factors were an increase of ¥9 million in current portion of long-term borrowings, despite a decrease of ¥112 million in accounts payable - others. Non-current liabilities increased by ¥214 million from the end of the previous fiscal year to ¥1,113 million. The factors were increases of ¥660 million in bonds payable and ¥160 million in long-term borrowings, despite a decrease of ¥606 million in convertible-bond-type bonds with share acquisition rights.

Net assets decreased by ¥423 million from the end of the previous fiscal year to ¥856 million. The main factors were a decrease in retained earnings of ¥520 million caused by the recording of loss

attributable to owners of parent and other factors, despite increases of ¥45 million in share capital and ¥45 million in capital surplus, as a result of the exercise of share acquisition rights.

As a result, the equity ratio was 41.2%.

(ii) Overview of cash flows

Cash and cash equivalents (“cash”) as of June 30, 2024 decreased by ¥566 million from December 31, 2023 to ¥1,301 million.

The status of cash flows during the six months ended June 30, 2024 are as follows.

Cash flows from operating activities

Net cash used in operating activities amounted to ¥790 million (¥142 million used in the same period of the previous fiscal year). This was mainly due to loss before income taxes of ¥519 million and increase in advance payments to suppliers of ¥260 million.

Cash flows from investing activities

Net cash used in investing activities amounted to ¥9 million (¥3 million used in the same period of the previous fiscal year). This was mainly due to purchase of property, plant and equipment of ¥8 million.

Cash flows from financing activities

Net cash provided by financing activities amounted to ¥233 million (¥46 million provided in the same period of the previous fiscal year). This was mainly due to proceeds from issuance of bonds of ¥660 million, proceeds from long-term borrowings of ¥170 million and proceeds from issuance of shares resulting from exercise of share acquisition rights of ¥65 million, despite redemption of convertible bonds of ¥666 million

(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 June 30, 2024, the Company’s cash and deposits stood at ¥1,301 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. Semi-annual consolidated financial statements and significant notes thereto

(1) Semi-annual consolidated balance sheets

(Thousands of yen)

	As of December 31, 2023	As of June 30, 2024
Assets		
Current assets		
Cash and deposits	1,867,264	1,301,058
Accounts receivable - trade	117,144	123,317
Supplies	87,863	103,521
Advance payments to suppliers	17,192	277,793
Other	48,495	42,188
Total current assets	2,137,959	1,847,879
Non-current assets		
Property, plant and equipment	10,010	14,328
Intangible assets		
Contract-related intangible assets	82,285	61,714
Other	4,224	3,757
Total intangible assets	86,510	65,471
Investments and other assets		
Other	150,191	150,763
Allowance for doubtful accounts	(11,301)	(12,836)
Total investments and other assets	138,890	137,926
Total non-current assets	235,411	217,726
Total assets	2,373,371	2,065,605
Liabilities		
Current liabilities		
Current portion of long-term borrowings	9,524	19,048
Accounts payable - other	161,362	49,045
Income taxes payable	11,708	10,549
Other	11,412	17,008
Total current liabilities	194,008	95,651
Non-current liabilities		
Bonds payable	–	660,000
Convertible-bond-type bonds with share acquisition rights	606,122	–
Long-term borrowings	269,476	429,952
Other	24,000	24,000
Total non-current liabilities	899,598	1,113,952
Total liabilities	1,093,606	1,209,603
Net assets		
Shareholders' equity		
Share capital	831,617	877,469
Capital surplus	2,889,857	2,935,708
Retained earnings	(2,442,372)	(2,963,070)
Treasury shares	(0)	(0)
Total shareholders' equity	1,279,101	850,107
Accumulated other comprehensive income		
Valuation difference on available-for-sale securities	(36)	(34)
Total accumulated other comprehensive income	(36)	(34)
Share acquisition rights	699	5,929
Total net assets	1,279,764	856,001
Total liabilities and net assets	2,373,371	2,065,605

(2) Semi-annual consolidated statements of income and consolidated statements of comprehensive income**Semi-annual consolidated statements of income**

(Thousands of yen)

	Six months ended June 30, 2023	Six months ended June 30, 2024
Net sales	187,710	223,522
Cost of sales	14,696	18,531
Gross profit	173,014	204,990
Selling, general and administrative expenses		
Research and development expenses	294,752	521,402
Other	136,614	133,432
Total selling, general and administrative expenses	431,366	654,835
Operating loss	(258,352)	(449,844)
Non-operating income		
Interest income	6	4
Foreign exchange gains	6,275	5,732
Other	11	14
Total non-operating income	6,292	5,751
Non-operating expenses		
Interest expenses	1,225	2,103
Share issuance costs	1,007	–
Commission expenses	255	119
Share issuance costs	–	8,686
Other	42	4,284
Total non-operating expenses	2,530	15,194
Ordinary loss	(254,590)	(459,287)
Extraordinary losses		
Loss on redemption of convertible bonds	–	60,612
Total extraordinary losses	–	60,612
Loss before income taxes	(254,590)	(519,900)
Income taxes - current	797	797
Total income taxes	797	797
Loss	(255,387)	(520,697)
Loss attributable to non-controlling interests	(7,403)	–
Loss attributable to owners of parent	(247,983)	(520,697)

Semi-annual consolidated statements of comprehensive income

(Thousands of yen)

	Six months ended June 30, 2023	Six months ended June 30, 2024
Loss	(255,387)	(520,697)
Other comprehensive income		
Valuation difference on available-for-sale securities	191	2
Total other comprehensive income	191	2
Comprehensive income	(255,196)	(520,695)
Comprehensive income attributable to		
Comprehensive income attributable to owners of parent	(247,792)	(520,695)
Comprehensive income attributable to non-controlling interests	(7,403)	–

(3) Semi-annual consolidated statements of cash flows

(Thousands of yen)

	Six months ended June 30, 2023	Six months ended June 30, 2024
Cash flows from operating activities		
Loss before income taxes	(254,590)	(519,900)
Depreciation	23,206	24,398
Share-based payment expenses	7,093	7,429
Loss on redemption of convertible bonds	–	60,612
Interest income	(6)	(4)
Interest expenses	1,225	2,103
Commission expenses	255	119
Foreign exchange losses (gains)	(1,266)	(1,847)
Share issuance costs	1,007	–
Share issuance costs	–	8,686
Decrease (increase) in trade receivables	67,843	(6,172)
Decrease (increase) in inventories	(30,463)	(15,658)
Increase (decrease) in allowance for doubtful accounts	–	1,535
Increase (decrease) in accounts payable - other	60,234	(110,537)
Decrease (increase) in advance payments to suppliers	(13,924)	(260,600)
Other, net	(638)	22,715
Subtotal	(140,022)	(787,120)
Interest received	6	4
Interest paid	(1,073)	(2,084)
Income taxes paid	(1,592)	(1,594)
Net cash provided by (used in) operating activities	(142,683)	(790,794)
Cash flows from investing activities		
Purchase of property, plant and equipment	(3,428)	(8,487)
Purchase of intangible assets	–	(1,100)
Decrease (increase) in guarantee deposits	(316)	–
Net cash provided by (used in) investing activities	(3,744)	(9,587)
Cash flows from financing activities		
Proceeds from long-term borrowings	31,000	170,000
Repayments of long-term borrowings	(60,000)	–
Proceeds from issuance of bonds	–	660,000
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	75,879	65,153
Purchase of treasury share acquisition rights	–	(699)
Purchase of treasury shares	(0)	–
Commission expenses paid	(272)	(226)
Net cash provided by (used in) financing activities	46,606	233,862
Effect of exchange rate change on cash and cash equivalents	256	314
Net increase (decrease) in cash and cash equivalents	(99,563)	(566,205)
Cash and cash equivalents at beginning of period	2,334,668	1,867,264
Cash and cash equivalents at end of period	2,235,105	1,301,058

(4) Notes to semi-annual consolidated financial statements**(Notes on premise of going concern)**

Not applicable.

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

We exercised the 12th series of share acquisition rights in the first six months of the fiscal year ending December 31, 2024. As a result, share capital and legal capital surplus respectively increased by ¥45,851 thousand, and as of June 30, 2024, share capital stood at ¥877,469 thousand and legal capital surplus stood at ¥2,935,708 thousand.

(Notes on segment information)

[Segment information]

Six months ended June 30, 2023

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

Six months ended June 30, 2024

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

(Subsequent events)

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

There was partial exercise of the 12th series of share acquisition rights issued by the Company on June 3, 2024 following the end of the sixth months ended June 30, 2024. An overview of the exercise of such share acquisition rights is as follows.

12th series of share acquisition rights

1. Number of units of share acquisition rights exercised	29,000 units
2. Type and number of shares issued	Common shares: 2,900,000 shares
3. Increase in share capital	¥117,665 thousand
4. Increase in legal capital surplus	¥117,665 thousand