Translation

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May 13, 2024

Consolidated Financial Results for the Three Months Ended March 31, 2024 (Based on Japanese GAAP)

Company name: D.Western Therapeutics Institute, Inc.
Listing: Tokyo
Securities code: 4576
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Scheduled date to file quarterly securities report: May 13, 2024
Scheduled date to commence dividend payments: –
Preparation of supplementary material on quarterly financial results: No
Holding of quarterly financial results meeting: No

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

1. Consolidated financial results for the three months ended March 31, 2024 (from January 1, 2024 to March 31, 2024)

(1) Consolidated operating results (cumulative)

(Percentages indicate year-on-year changes.)

	Net sales		Operating profit		Ordinary profit		Profit attributable to owners of parent	
Three months ended	Millions of yen	%	Millions of yen	%	Millions of yen	%	Millions of yen	%
March 31, 2024	104	16.5	(318)	–	(320)	–	(320)	–
March 31, 2023	90	(18.0)	(101)	–	(101)	–	(97)	–

Note: Comprehensive income For the three months ended March 31, 2024 ¥(320) million [–%]
For the three months ended March 31, 2023 ¥(101) million [–%]

	Earnings per share	Diluted earnings per share
Three months ended	Yen	Yen
March 31, 2024	(9.99)	–
March 31, 2023	(3.14)	–

(2) Consolidated financial position

	Total assets	Net assets	Equity ratio
As of	Millions of yen	Millions of yen	%
March 31, 2024	2,117	958	45.3
December 31, 2023	2,373	1,279	53.9

Reference: Equity
As of March 31, 2024 ¥958 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	–				
Fiscal year ending December 31, 2024 (Forecast)		0.00	–	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) Changes in significant subsidiaries during the three months ended March 31, 2024 (changes in specified subsidiaries resulting in the change in scope of consolidation): 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 March 31, 2024	32,128,012 shares
As of December 31, 2023	32,128,012 shares

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

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

(iii) Average number of shares during the period

Three months ended March 31, 2024	32,127,726 shares
Three months ended March 31, 2023	31,181,731 shares

* Quarterly financial results reports are exempt from quarterly 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 three months of the fiscal year ending December 31, 2024" on page 4 of the attached materials.

Attached Material

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

(1) Explanation of operating results

During the first three 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. The target date for completion of the review was set at July 11, 2024. 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 for administering medication to patients. 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 other companies.

As a result of the above, royalty income, etc. from products on the market drove net sales of ¥104 million (up 16.5% year on year), while cost of sales came to ¥9 million (up 24.5% year on year).

Selling, general and administrative expenses were ¥414 million (up 125.6% year on year). The breakdown of selling, general and administrative expenses was research and development expenses of ¥346 million (up 206.5% year on year), associated with increased development expenses of H-1337 and DWR-2206, and other selling, general and administrative expenses of ¥67 million (down 4.2% year on year).

This resulted in operating loss of ¥318 million (compared to operating loss of ¥101 million in the same period of the previous fiscal year), ordinary loss of ¥320 million (compared to ordinary loss of ¥101 million in the same period of the previous fiscal year), and loss attributable to owners of parent of ¥320 million (compared to loss attributable to owners of parent of ¥97 million in the same period of the previous fiscal year).

The state of new drug candidate compound development in the first three 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 terms of joint development, we are forging ahead with multiple initiatives, such as a targeted protein degradation project with UBiENCE Inc., and an ophthalmic condition drug discovery project with RaQualia Pharma Inc.

(2) Explanation of financial position

Total assets decreased by ¥256 million from the end of the previous fiscal year to ¥2,117 million. Current assets decreased by ¥251 million from the end of the previous fiscal year to ¥1,886 million. The main factors were a decrease of ¥479 million in cash and deposits, despite an increase of ¥213 million in advance payments to suppliers, and other factors. Non-current assets decreased by ¥4 million from the end of the previous fiscal year to ¥230 million. The main factors were a decrease of ¥10 million in contract-related intangible assets, despite an increase of ¥6 million in property, plant and equipment, and other factors.

Liabilities increased by ¥64 million from the end of the previous fiscal year to ¥1,158 million. Current liabilities decreased by ¥39 million from the end of the previous fiscal year to ¥154 million. The main factors were a decrease of ¥42 million in accounts payable - other, and other factors. Non-current liabilities increased by ¥104 million from the end of the previous fiscal year to ¥1,003 million. The factor was an increase of ¥104 million in long-term borrowings.

Net assets decreased by ¥320 million from the end of the previous fiscal year to ¥958 million. The main factors were a decrease of ¥320 million in retained earnings due to loss attributable to owners of parent incurred, and other factors.

As a result, the equity ratio was 45.3%.

(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.

2. Quarterly consolidated financial statements and significant notes thereto

(1) Quarterly consolidated balance sheets

(Thousands of yen)

	As of December 31, 2023	As of March 31, 2024
Assets		
Current assets		
Cash and deposits	1,867,264	1,387,578
Accounts receivable - trade	117,144	152,182
Supplies	87,863	84,842
Advance payments to suppliers	17,192	230,570
Other	48,495	31,775
Total current assets	2,137,959	1,886,949
Non-current assets		
Property, plant and equipment	10,010	16,224
Intangible assets		
Contract-related intangible assets	82,285	72,000
Other	4,224	3,990
Total intangible assets	86,510	75,990
Investments and other assets		
Other	150,191	150,130
Allowance for doubtful accounts	(11,301)	(11,924)
Total investments and other assets	138,890	138,205
Total non-current assets	235,411	230,420
Total assets	2,373,371	2,117,369
Liabilities		
Current liabilities		
Current portion of long-term borrowings	9,524	14,286
Accounts payable - other	161,362	118,970
Income taxes payable	11,708	5,158
Other	11,412	16,312
Total current liabilities	194,008	154,727
Non-current liabilities		
Convertible-bond-type bonds with share acquisition rights	606,122	606,122
Long-term borrowings	269,476	373,714
Other	24,000	24,000
Total non-current liabilities	899,598	1,003,836
Total liabilities	1,093,606	1,158,564
Net assets		
Shareholders' equity		
Share capital	831,617	831,617
Capital surplus	2,889,857	2,889,857
Retained earnings	(2,442,372)	(2,763,226)
Treasury shares	(0)	(0)
Total shareholders' equity	1,279,101	958,248
Accumulated other comprehensive income		
Valuation difference on available-for-sale securities	(36)	(142)
Total accumulated other comprehensive income	(36)	(142)
Share acquisition rights	699	699
Total net assets	1,279,764	958,805
Total liabilities and net assets	2,373,371	2,117,369

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

Quarterly consolidated statements of income (cumulative)

(Thousands of yen)

	Three months ended March 31, 2023	Three months ended March 31, 2024
Net sales	90,000	104,819
Cost of sales	7,331	9,128
Gross profit	82,668	95,690
Selling, general and administrative expenses		
Research and development expenses	113,175	346,863
Other	70,578	67,622
Total selling, general and administrative expenses	183,753	414,485
Operating loss	(101,085)	(318,795)
Non-operating income		
Interest income	6	4
Foreign exchange gains	1,201	2,645
Other	11	14
Total non-operating income	1,219	2,664
Non-operating expenses		
Interest expenses	626	869
Share issuance costs	665	–
Loss on disposal of supplies	–	2,748
Other	172	704
Total non-operating expenses	1,464	4,323
Ordinary loss	(101,330)	(320,454)
Loss before income taxes	(101,330)	(320,454)
Income taxes - current	398	398
Total income taxes	398	398
Loss	(101,729)	(320,853)
Loss attributable to non-controlling interests	(3,867)	–
Loss attributable to owners of parent	(97,861)	(320,853)

Quarterly consolidated statements of comprehensive income (cumulative)

(Thousands of yen)

	Three months ended March 31, 2023	Three months ended March 31, 2024
Loss	(101,729)	(320,853)
Other comprehensive income		
Valuation difference on available-for-sale securities	94	(106)
Total other comprehensive income	94	(106)
Comprehensive income	(101,634)	(320,959)
Comprehensive income attributable to		
Comprehensive income attributable to owners of parent	(97,766)	(320,959)
Comprehensive income attributable to non-controlling interests	(3,867)	–

(3) Quarterly consolidated statements of cash flows

Quarterly consolidated statements of cash flows are not prepared for the three months ended March 31, 2024. Depreciation (including amortization of intangible assets) for the three-month period under review is as follows:

	Three months ended March 31, 2023	Three months ended March 31, 2024
Depreciation	¥11,491 thousand	¥11,983 thousand

(4) Notes to quarterly consolidated financial statements

(Notes on premise of going concern)

Not applicable.

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

Not applicable.

(Segment information)

Three months ended March 31, 2023

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

Three months ended March 31, 2024

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

(Subsequent events)

(Issuance of new shares as restricted stock compensation)

The Company resolved, at a meeting of its Board of Directors held on April 11, 2024, to issue new shares as described below and completed payment on May 8, 2024.

1. Purpose and reason for issuance

At the Board of Directors meeting held on February 15, 2018, the Company resolved to introduce a stock compensation plan that restricted stocks are delivered to the Company's Directors (excluding outside Directors) and Directors of the Company's subsidiaries (excluding outside Directors) (the "Plan"). The purpose was for the Company's Directors (excluding outside Directors) and Directors of the Company's subsidiaries (excluding outside Directors) to share the benefits and risks of stock price fluctuations with shareholders and to further increase their motivation to contribute to the increase in stock price and corporate value.

In addition, at the 25th Ordinary General Meeting of Shareholders held on March 30, 2023, it was approved that the Company set the total amount of monetary remuneration claims to be paid to the Company's Directors (excluding Directors who serve as the Audit and Supervisory Committee Members and outside Directors) and Directors of the Company's subsidiaries (excluding outside Directors) under the Plan as compensation for restricted stocks at no more than ¥60 million per year.

2. Overview of issuance

Due date of payment	May 8, 2024
Class and number of shares to be issued	147,500 shares of common stock of the Company
Amount to be paid in per share	¥119 per share
Total amount of issuance	¥17,552,500
Amount to be incorporated into the stated capital	¥59.5 per share
Total amount to be incorporated into the stated capital	¥8,776,250
Offer or allotment method	Allotment of restricted stocks
Method of performance of contributions	Contribution of monetary remuneration claims in kind
Allottees, number thereof and number of shares to be allotted	The Company's Directors (excluding Directors who serve as the Audit and Supervisory Committee Members and outside Directors) two people 130,700 shares Directors of the Company's subsidiaries (excluding outside Directors) four people 16,800 shares
Period of restrictions on transfers	From May 8, 2024 to May 7, 2027
Other	The Company has filed a written notice of securities (yuka shoken tsuchisho) regarding the New Share Issuance in accordance with the Financial Instruments and Exchange Act.

3. Other

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, as of March 31, 2024, the Company's cash and deposits stood at ¥1,387 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.