D. Western Therapeutics Institute (DWTI) | 4576

Sponsored Research
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Sessa Investment Research

Net sales down on lower royalty income, but pipeline progress warrants attention

Summary

In Q1 FY2026/12, D. Western Therapeutics Institute, Inc. (DWTI, hereinafter "the Company") reported net sales of JPY 15 mn (-84.4% YoY). In terms of costs, the Company posted SG&A expenses of JPY 182 mn (-20.2% YoY), including R&D expenses of JPY 117 mn (-17.5% YoY). As a result, the Company recorded an operating loss of JPY 167 mn (loss of JPY 142 mn a year earlier), an ordinary loss of JPY 170 mn (loss of JPY 149 mn), and net loss attributable to owners of parent of JPY 170 mn (loss of JPY 150 mn).

■ Expectations for net sales growth

Q1 net sales fell on lower royalty income due to patent expiration. For TissueBlue™, the Company and licensee DORC agreed to extend their agreement for regions where patents remain in force and are discussing detailed terms. No royalties from this product were recorded in Q1 FY2026/12 net sales, and the Company plans to record the royalties in a lump sum upon the contract extension (already incorporated into the FY2026/12 forecast). In addition, the Company is co-developing Bondlido (development code: DW-5LBT) with MedRx, and the product has already received marketing approval in the US. In May, the Company reached a basic agreement with US pharmaceutical company Terrain Pharmaceuticals (Terrain) on a sales partnership in the US. This has moved preparations forward toward launch in H2 2026. The company will receive some performance-based distributions based on the revenue performance of this product (not currently incorporated into the FY2026/12 forecast).

■ Share price insights

The Company's share price has been weak recently, partly owing to lower Q1 FY2026/12 net sales. However, expectations for sales growth are rising based on the developments described above. From a medium-term perspective, the feasibility of the Company's goal of "launching one product per year from FY2026/12 onward" is rising. The first product in line is DW-5LBT. If the launch is successful, expectations for the Company to achieve this goal are likely to rise further. Under the current development schedule, the Company plans to launch DW-1002 in FY2027/12 and K-321 in FY2028/12. DWTI could strengthen its presence as one of the few drug discovery ventures in Japan with four successfully launched products.

Results currently reflect upfront development costs, but SIR believes that if launches proceed as planned, investor expectations for the Company as a drug discovery venture will rise further and be reflected in the share price.

(JPY mn, %, JPY)	Net Sales	YoY	Oper. Profit	YoY	Ord.Profit	YoY	Net Profit	YoY	EPS	DPS
FY2023/12	428	*(4.4)*	(798)	--	(796)	--	(812)	--	(25.56)	0.00
FY2024/12	471	*10.1*	(1,209)	--	(1,228)	--	(1,290)	--	(36.74)	0.00
FY2025/12	387	*(17.8)*	(619)	--	(630)	--	(632)	--	(13.19)	0.00
FY2026/12 CE	**300**	*(22.6)*	**(780)**	--	**(800)**	--	**(800)**	--	**(14.75)**	**0.00**
Q1 FY2025/12	96	*(7.7)*	(142)	--	(149)	--	(150)	--	(3.41)	--
Q1 FY2026/12	15	*(84.4)*	(167)	--	(170)	--	(170)	--	(3.14)	

Source: Compiled by SIR from the Company's annual securities report and earnings summary.
Note: Figures may differ from the Company's materials due to differences in SIR's financial data processing and the Company's reporting standards.

Q1 Follow-up

DWTI

Focus Points:

Drug discovery bio-venture with strengths in the kinase inhibitor mechanism and treatments for ophthalmic diseases such as glaucoma and ocular hypertension. Business model expanded to include in-license development and joint discovery/development.

Key Indicators	
Share price (5/25)	80
52WH (25/9/26)	181
52WL (26/5/20)	76
10YH (17/2/21)	857
10YL(24/8/5)	60
Shrs out. (mn shrs)	57.483
Mkt cap (JPY bn)	4.599
EV (JPY bn)	3.652
26/3 Equity ratio (act)	66.8%
25/12 ROE (act)	--
25/12 P/B (act)	3.50x
26/12 P/E (CE)	--
26/12 EV/EBITDA (CE)	--
26/12 DY (CE)	--

1 Year Share price trend



Source: TradingView

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This report was prepared by Sessa Partners on behalf of D. Western Therapeutics Institute, Inc. Please refer to the legal disclaimer at the end for details.

Q1 FY2026/12 Performance Trends

■ **Results overview**

● **Net sales/royalty income**

Net sales came to JPY 15 mn (-84.4% YoY). This consisted of royalties from steady Japan/Asia sales of the launched GLA-ALPHA® combination ophthalmic solution. The drop mainly reflected (1) lower royalties after the December 2025 expiration of non-US patents for Brilliant Blue G (BBG), an ophthalmic surgical staining dye, and (2) the end of overseas royalties from GLANATEC® in 2025.

For TissueBlue™, the Company and licensee DORC agreed to extend their agreement for regions where patents remain in force and are discussing detailed terms. No royalties from this product were recorded in Q1 FY2026/12 net sales, and the Company plans to record the royalties in a lump sum upon execution of the contract extension.

● **SG&A expenses/R&D expenses**

SG&A expenses came to JPY 182 mn (-20.2% YoY). R&D expenses amounted to JPY 117 mn (-17.5% YoY), as development expenses for H-1337 and DWR-2206 fell versus a year earlier. Other SG&A expenses came to JPY 64 mn (-24.7% YoY), mainly owing to lower personnel expenses.

● **Losses**

As a result, the Company recorded an operating loss of JPY 167 mn (loss of JPY 142 mn a year earlier), an ordinary loss of JPY 170 mn (loss of JPY 149 mn), and net loss attributable to owners of parent of JPY 170 mn (loss of JPY 150 mn).

Consolidated financial summary and trends

JPY mn, % [J-GAAP]	FY25/12 Q1(act)	FY26/12 Q1(act)	CHG	FY25/12 (act)	FY26/12 Initial forecast	CHG
Net sales	**96**	**15**	**(81)**	**387**	**300**	**(87)**
YoY	**(7.7)**	**(84.4)**		**(17.8)**	**(17.8)**	
Cost of sales	10	-	(10)	39		
Gross profit	86	15	(71)	349		
SG&A	228	182	(46)	969		
・R&D expenses	**142**	**117**	**(24)**	**669**	**780**	**111**
% of Net sales	***147.3%***	***777.7%***		***172.9%***		
Other SG&A expenses	86	64	(21)	298		
Operating income (loss)	**(142)**	**(167)**	**(25)**	**(619)**	**(780)**	**(161)**
Ordinary income (loss)	(149)	(170)	(20)	(630)	(800)	(170)
Net income (loss) attributable to owners of parent	**(150)**	**(170)**	**(20)**	**(632)**	**(800)**	**(168)**
Major Balance Sheet Indicators		**FY26 Q1**	**◀◀**	**FY25/12**		
Cash and deposits		**1,539**	**(169)**	**1,709**		
Total assets		1,968	(200)	2,169		
Total liabilities		654	(79)	734		
Total net assets		1,314	(121)	1,435		
Equity ratio		66.7%		66.1%		

Source: Compiled by SIR from the Company's annual securities report and earnings summary.
Note: Figures may differ from the Company's materials due to differences in SIR's financial data processing and the Company's reporting standards.

Development Pipeline

■ **Basic agreement reached on US sales partnership for DW-5LBT**

The Company has received notice from MedRx Co., Ltd. (MedRx) regarding Bondlido (development code: DW-5LBT), a lidocaine tape formulation that the two companies jointly developed in the US and have received marketing approval for. According to MedRx, it has agreed on the basic terms of a US sales partnership with US pharmaceutical company Terrain Pharmaceuticals (Terrain; May 15, 2026 press release). MedRx and Terrain plan to finalize the detailed terms of an exclusive sales license agreement and enter into a formal agreement within 60 days. They also plan to move forward with preparations for launch in H2 2026. Under its agreement with MedRx, the Company will receive some performance-based distributions based on the revenue performance of this product. These performance-based distributions are not currently incorporated into the FY2026/12 forecast because the future revenue remains uncertain.

■ **Development pipeline overview**

The Company's current pipeline is shown below. For H-1337, the Company signed an option agreement with Senju Pharmaceutical in March covering Japan, Asia, and other regions, and shifted its strategy to prioritize development in Japan.

Progress of development pipeline

Product code	Indication	Region	Overview of Development	License-out Partner
K-321	Fuchs endothelial corneal dystrophy	U.S. and Europe etc.	Phase III clinical trial	Kowa Co., Ltd.
DW-1002	Ophthalmic surgery staining dye	Japan	Phase III clinical trial	Wakamoto Pharmaceutical Co., Ltd.
		U.S.	Preparing for Application	DORC
DW-1001	Ophthalmic therapeutic agent (Undisclosed)	Japan	Phase I clinical trial	Rohto Pharmaceutical Co., Ltd
H-1337	Glaucoma and ocular hypertension	U.S. and Japan	Preparing for Phase III clinical trial	In-house development
H-1129	Keratoconjunctival diseases based on immune disorders	Japan	Preparing for Clinical Trials	In-house development
DW-5LBT	Neuropathic pain after shingles	U.S.	Approved; Basic agreement on sales partnership with US Terrain	Joint development with MEDRx Inc.
DWR-2206	Bullous Keratopathy	Japan	Phase II clinical trial	Joint development with ActualEyes Inc.

Source: Compiled by SIR from the Company's earnings summary etc.

● **K-321 (Indication: Fuchs endothelial corneal dystrophy; expanded indication for Ripasudil)**

Ripasudil hydrochloride hydrate, invented by the Company, has been suggested to act on kinases in the eye. As part of efforts to expand its indications, a Phase II clinical trial in the US targeting Fuchs endothelial corneal dystrophy began in 2019. This was followed by the start of a Phase III clinical trial in the US in 2022 and a global Phase III clinical trial including the US in 2023. Of the two ongoing global Phase III clinical trials, the observation period for the remaining trial concluded in March. As a result, follow-up observations for all global Phase III clinical trials are now fully completed, and data analysis is currently underway. As Fuchs endothelial corneal dystrophy progresses, it leads to corneal endothelial damage. Until now, treatment for corneal endothelial diseases associated with severe visual impairment has relied on corneal transplantation, representing a high unmet medical need for the development of effective therapeutic agents.

The Company aims to submit a US application in 2027, with approval and launch targeted for 2028 onward.

- **DW-1002 (Ophthalmic surgical staining dye, BBG)**

An ophthalmic surgical staining dye is a drug used during eye surgery. The Company has granted DORC an exclusive sublicense covering the entire world outside Japan, and since 2010 DORC has manufactured and sold the product in Europe and other regions under the brand names ILM-Blue® and MembraneBlue-Dual®. In 2020, DORC also began selling the single-agent product TissueBlue™ in the US. Preparations are currently underway for filing approval applications, as a single-agent product in Japan and as a combination product in the US. In Japan, the Company is consulting with the PMDA on quality and specification issues related to the use of US approval data. Approval applications are scheduled in both Japan and the US during FY2026/12, with the aim of obtaining approval and launching the product in 2027 onward.

- **DW-1001 (Indication: undisclosed)**

This pipeline product is an ophthalmic therapeutic agent in-licensed from a UK company in 2015. The Company aims to reposition a compound already marketed for other indications for use in ophthalmology. Accordingly, development costs and risks are expected to be relatively low.

In 2019, the Company licensed exclusive commercialization rights in Japan to Rohto Pharmaceutical Co., Ltd. Rohto advanced non-clinical studies and completed a domestic Phase I clinical trial with favorable results in 2022.

- **H-1337 (Indications: Glaucoma and ocular hypertension)**

This pipeline product targets glaucoma and ocular hypertension and was optimized from a seed compound in the Company's compound library centered on protein kinase inhibitors. The Company is conducting its first in-house clinical development program for this product, and the late Phase II clinical trial in the US was completed in August 2024. The trial results were favorable, confirming the product's efficacy, and no serious adverse events were observed in terms of safety.

Following the conclusion of a capital and business alliance agreement with Senju Pharmaceutical Co., Ltd. on March 25, 2026, the Company decided to advance development in Japan in addition to the US, which had been the focus previously. The Company plans to begin from Phase III clinical trials in Japan as well. Through consultations with the PMDA, the Company plans to confirm whether the clinical trial data accumulated in the US to date, as well as the data being prepared for the Phase III clinical trial can be utilized, while also moving ahead with the various studies and clinical trial implementation framework required to meet Japanese regulatory requirements.

- **H-1129 (Indications: Therapeutic agent for keratoconjunctival diseases based on immune disorders (undisclosed))**

This pipeline product was optimized based on seed compounds from the Company's compound library centered on protein kinase inhibitors. It had been under development as a glaucoma treatment until 2019, but development was discontinued following Phase III clinical trials in Japan. Subsequently, from the perspective of effectively utilizing intellectual property and realizing the potential of kinase inhibitors, the Company explored applications to other indications, and in July 2025 added it to the pipeline as a new therapeutic agent for keratoconjunctival diseases based on immune disorders. Preparations for clinical trials are currently underway.

(Continued from the previous page)

The Company has conducted joint research with Keio University (hereinafter "Keio"), and has jointly filed a patent application with Keio for uses related to the development of H-1129 for keratoconjunctival diseases. In April 2026, the Company entered into a license agreement with Keio that gives the Company exclusive worldwide rights to use this patent application. Under the agreement, the Company will pay Keio an upfront payment, milestone fees based on development progress, and royalties after sales begin.

SIR believes this agreement will help boost the value of the Company's pipeline over the medium to long term.

- **DW-5LBT (Indication: Post-herpetic neuralgia; product name: Bondlido)**

This pipeline product is a novel lidocaine patch that uses MedRx Co., Ltd.'s proprietary Ionic Liquid Transdermal System (ILTS) technology. The product targets the market for the lidocaine patch Lidoderm and was developed with a view to expanding into additional new markets. MedRx advanced development of the product as a treatment for post-herpetic neuralgia, and the Company began joint development in 2020. The product subsequently received US approval in September 2025. In May 2026, MedRx reached an agreement on the basic terms of a US sales partnership with US-based Terrain. MedRx and Terrain plan to finalize the detailed terms of an exclusive sales license agreement and enter into a formal agreement within 60 days. They also plan to move forward with preparations for launch in H2 2026. Under its agreement with MedRx, the Company will receive some performance-based distributions based on the revenue performance of this product.

- **DWR-2206 (Indication: Bullous keratopathy)**

This pipeline product is a regenerative cell therapy for the treatment of bullous keratopathy. It is designed to regenerate the corneal endothelium by injecting into the anterior chamber of the eye a suspension containing cultured human corneal endothelial cells and a ROCK inhibitor. ActualEyes Inc. is advancing development, and the Company began joint development in 2022. This is the Company 's first regenerative medicine product. The domestic Phase II clinical trial began in March 2024, and the patient observation period ended in November 2025. So far, no major adverse events or treatment-related serious adverse events have been reported, and the efficacy data suggest improvement in visual acuity. The Company is now analyzing the data and preparing for a Phase III clinical trial.

New Share Issuance

■ New shares issuance in FY2026/12

On April 10, 2026, the Company raised JPY 199.9 mn through the issuance of 2,150,500 new shares under its capital and business alliance with Senju Pharmaceutical Co., Ltd., a company with strengths in ophthalmology. After deducting estimated issuance expenses, the Company raised JPY 195.0 mn.

In July 2025, the Company issued its 13th series of stock acquisition rights with an exercise price adjustment clause through a third-party allotment. These stock acquisition rights cover the issuance of 10,000,000 new shares (exercise period: August 1, 2025 to August 2, 2027). As of the end of April 2026, the Company had issued 9,090,200 shares, with an exercise ratio of 90.9%.

New share issuance in FY2026/12

Period	Total Number of Issued Shares			Amount Raised (JPY mn)	Remarks
	Change	Balance	Treasury Shares		
End of Dec, 2025		54,251,712	286		
Feb, 2026	105,000	54,356,712		9.5	Exercise of the 13th Series of Stock Acquisition Rights
March 2026	475,000	54,831,712		40.2	〃
End of March 2026		54,831,712	11,386		
Apr. 10, 2026	2,150,500	56,982,212		9,090.2 *	Third-party allotment
May 14, 2026	501,200	57,483,412			Issuance of new shares as stock compensation
as of May 14, 2026		57,483,412			

* Net proceeds after deducting the estimated amount of issuance expenses.
Source: Compiled by SIR from the Company's earnings summary and press release.

Share Price Insights

Share price trends

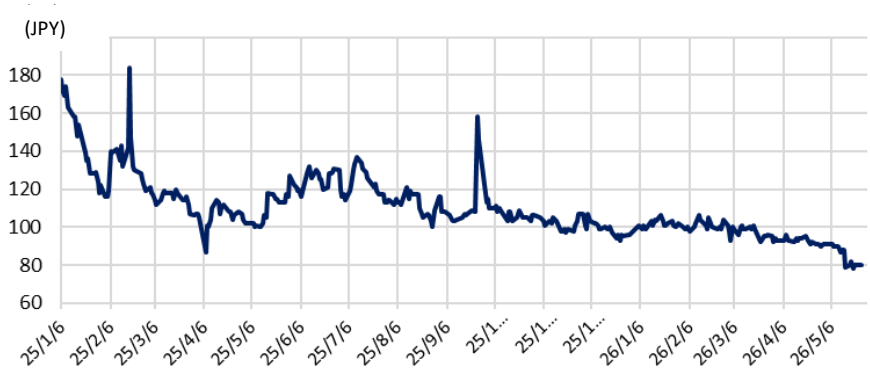
The Company's share price hit a limit-up high of JPY 158 on September 25, 2025. The market reacted positively to the press release announced the same day, titled "DW-5LBT 'Bondlido' Approved in the US for the Treatment of Post-Herpetic Neuralgia." However, the rally proved temporary, and the share price subsequently settled around JPY 100. Since late March 2026, the share price has remained weak owing to factors such as the new share issuance and the sharp drop in net sales in Q1.

For DW-5LBT, the basic agreement with US-based Terrain on a sales agreement has made the path toward launch in H2 2026 clearer. For TissueBlue™, the Company has agreed with licensee DORC to extend the contract for regions where patents remain in force. No royalties were recorded as part of net sales in Q1 FY2026/12, and the Company plans to record them in a lump sum after the formal contract extension is executed.

From a medium-term perspective, the feasibility of the Company's goal of "launching one product per year from FY2026/12 onward" is rising. The first product in line is DW-5LBT. If the launch is successful, expectations for the Company to achieve this goal are likely to rise further. Under the current development schedule, the Company plans to launch DW-1002 in FY2027/12 and K-321 in FY2028/12. The Company could strengthen its presence as one of the few drug discovery ventures in Japan with four successfully launched products.

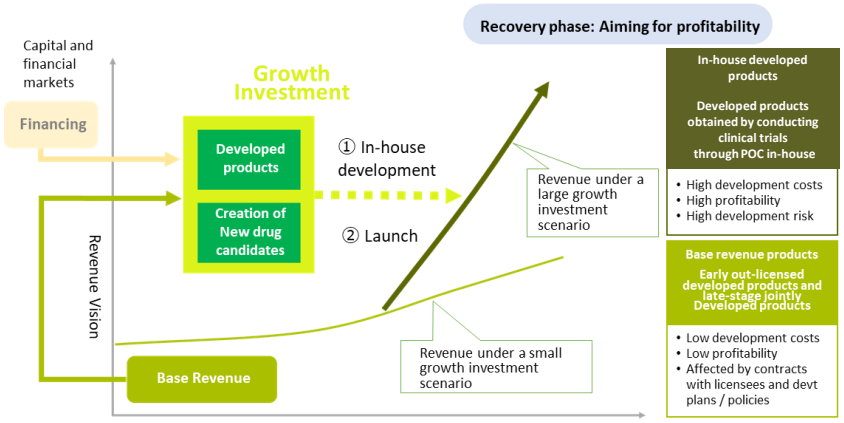
Results currently reflect upfront development costs, but SIR believes that if launches proceed as planned, investor expectations for the Company as a drug discovery venture will rise further and be reflected in the share price.

Share price trends from January 2025



Source: Compiled by SIR from SPEEDA data.

Growth investment and revenue image



Source: The Company's "Business Plan and Growth Potential."

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