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**D.WESTERN THERAPEUTICS INSTITUTE**

**FY12/24**

**Financial Results Briefing Materials**



February 10, 2025

D. Western Therapeutics Institute, Inc.

Stock Code: 4576

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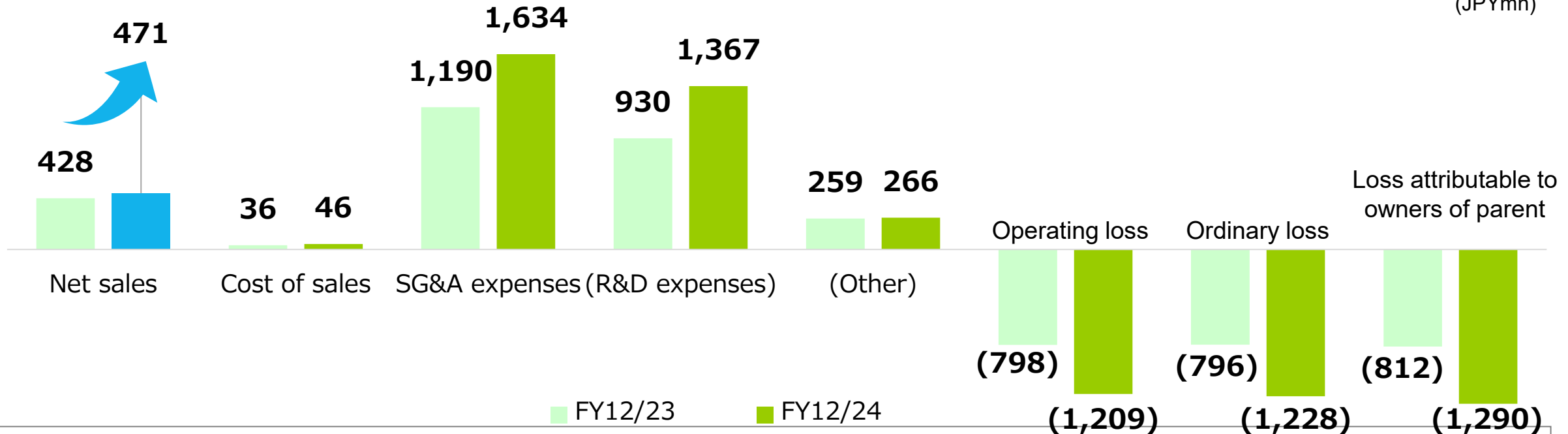
1. FY12/24 Financial Results
  2. Progress of Business in FY12/24
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- (Reference) Business Overview

# 1. FY12/24 Financial Results

January 1–December 31, 2024

# Consolidated Statement of Income (YoY comparison)

(JPYmn)



## Net sales

- Despite the loss of domestic royalty income from GLANATEC in September, sales increased 10.1% YoY, reaching the highest level in the last five years due to growth in DW-1002 sales.
- On a standalone basis, DW-1002 sales increased 21.0% YoY due to an increase in volume and the impact of a weaker yen. GLA-ALPHA also grew steadily, increasing 74.9% YoY.

## R&D expenses

- R&D expenses rose 47.0% YoY due to increased spending on development of H-1337 (Phase IIb study in the US) and DWR-2206.

# Consolidated Statement of Income (vs. full-year forecast)

(JPYmn)

		FY12/23	FY12/24		% of initial forecast	Primary factors
		FY results	FY forecast (out Feb.9)	FY results		
Net sales		428	400	471	17.9%	<ul style="list-style-type: none"> <li>Strong royalties for DW-1002 and GLA-ALPHA</li> <li>GLANATEC (Japan) ended royalty income in September, but the impact of the combination drug was minimal, and revenue was substantial</li> </ul>
SG&A expenses		1,190		1,634		
	R&D expenses	930	1,600	1,367	△14.5%	<ul style="list-style-type: none"> <li>No payment milestone for DW-5LBT</li> <li>Development expenses for H-1337 was less than expected.</li> </ul>
	Other SG&A expenses	259		266		<ul style="list-style-type: none"> <li>As planned</li> </ul>
Operating loss		△798	△1,500	△1,209	—	
Ordinary loss		△796	△1,510	△1,228	—	
Loss attributable to owners of parent		△812	△1,510	△1,290	—	<ul style="list-style-type: none"> <li>Loss on redemption of convertible bonds of JPY60mn in extraordinary losses</li> </ul>



# Consolidated Statement of Income

As of December 31, 2024  
(change compared to December 31, 2023)

(JPYmn)

		<b>Current liabilities</b>
		<b>132 (-61)</b>
		<b>Non-current liabilities</b>
		<b>802 (-96)</b>
<b>Cash and deposits</b>		
<b>1,126 (-741)</b>		
<b>Accounts receivable trade</b>	<b>125 (+7)</b>	
<b>Other current assets</b>	<b>224 (-70)</b>	
<b>Non-current assets</b>	<b>194 (-41)</b>	
		<b>Net assets</b>
		<b>733 (-545)</b>

## Cash and deposits

- Declined due mainly to R&D expenditures
- Increase due to the exercise of the 12th series of stock acquisition rights

## Supplies

- Increase in advances paid for the development of H-1337 and DWR-2206, increase in uncollected consumption tax

## Non-current assets

- JPY41mn in amortization of intangible assets related to the licensing agreement for DW-1002 (Europe)

## Current liabilities

- JPY76mn decline in accounts payable due to H-1337 and DWR-2206 development costs JPY9mn increase in current portion of long-term borrowings

## Non-current liabilities

- Redemption of convertible bonds of JPY606mn from the issuance of corporate bonds of JPY660mn and redemption of corporate bonds of JPY357mn through the exercise of stock acquisition rights
- JPY206mn increase in long-term borrowings due to loans to fund the development of DWR-2206

## Net assets

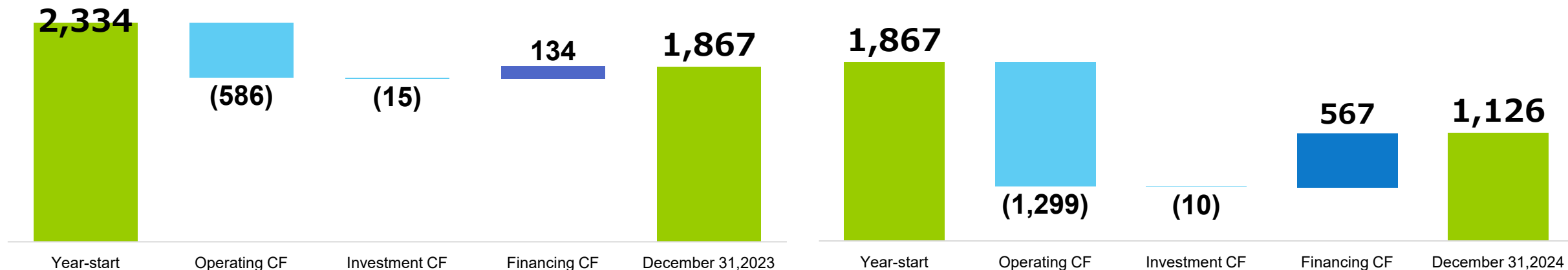
- Recorded a loss attributable to owners of parent of JPY1.2bn
- Recorded JPY371mn each in capital and capital reserves due to exercise of stock acquisition rights

# Consolidated Cash Flow Statement

FY 12/23

FY 12/24

(JPYmn)



## Cash flow from operating activities

- JPY1.2bn outflow due to the recording of loss before income taxes

## Cash flow from investing activities

- JPY9mn outflow from acquisition of property, plant and equipment

## Cash flow from financing activities

- JPY710mn proceeds from the exercise of stock acquisition rights, JPY660mn proceeds from issuance of bonds, JPY226mn proceeds from long-term borrowings
- JPY666mn redemption of convertible bonds, JPY357mn redemption of bonds,

**On-hand liquidity on December 31, 2024 consisted only of JPY1.1bn in cash and deposits (no securities)**

## 【Exercise status of Series 12 Stock Acquisition Rights】

- ✓ Number of shares exercised 9,350,000 (71.9%)
- ✓ Total amount raised JPY727mn

(As of Dec. 31, 2024)

\*The exercise was completed on February 7, 2025 (see page 35).

## **2. Progress of Business in FY12/24**

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# Development Pipeline in FY12/24

products on market	Region	Current state
GLANATEC® (Single drug)	Japan, Asia	Royalty ended in September in Japan
GLA-ALPHA® (Combination drug)	Japan, Asia	Growth in royalties in Japan, approved in Thailand
DW-1002 (Single drug)	Europe, U.S.	Strong due to yen depreciation and volume increase
DW-1002 (Combination drug)	Europe, etc.	Strong due to yen depreciation and volume increase

Products	Region	Current state	
K-321	U.S., etc.	Global Phase III ongoing	
DW-1002	Combination	U.S.	
	Single	China	Regulatory review underway
		Japan	Negotiations with the regulatory authority and examination underway for application filing
DW-1001	Japan		
H-1337	U.S.	Completion of dosing in the Phase IIb study in August, topline data released in November	
DW-5LBT	U.S.	Reapplied in January 2024, received CRL in July,	
DWR-2206	Japan	Submitted a Clinical Trial plan Notification for Phase II in March, Completion of dosing in December	

# Achievement of 2024 event calendar

H-1337

Publish top-line data of Phase IIb study in US



**achieved** Good results

DW-5LBT

U.S. reapplication ~ Approval, Launch



**delay** Received CRL,  
Preparing for reapplication

DWR-2206

Start of Phase II study in Japan



**achieved** Dosing completed for subject

DW-1002

Application, approval and Launch in China, Application in Japan



**delay**

**New projects**

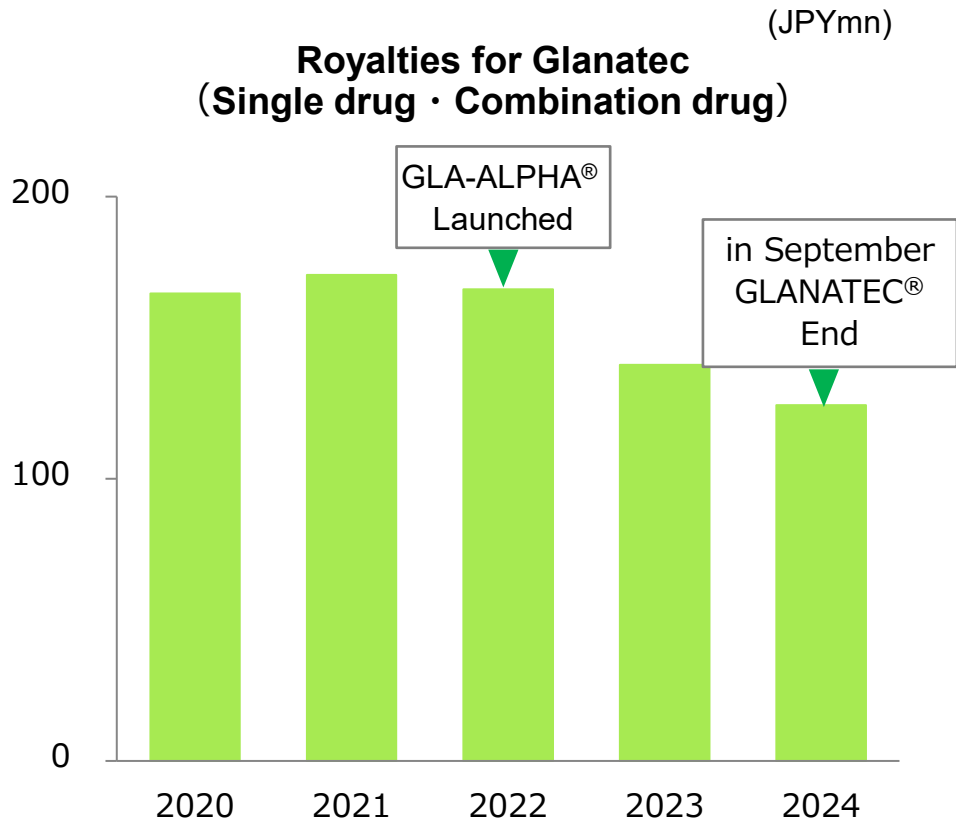
Research progress (including new collaborations)

⇒ Multiple joint research projects are underway

## 2-1. Successful launch (commercialization)



# Glaucoma Treatment Ripasudil hydrochloride hydrate



## GLANATEC® Ophthalmic Solution 0.4%

- ✓ In Japan, royalty income ended in September 2024
- ✓ To receive royalties a little overseas



## GLA-ALPHA® Combination ophthalmic solution

Combination drug with ripasudil hydrochloride hydrate and brimonidine tartrate

- ✓ Significant YoY increase
- ✓ Overseas expansion (Approval: Thailand in December 2024, Application: Singapore in February 2024 and Malaysia in April 2024, Applications for other Asian countries are in preparation)
- ✓ Japan: Sales projected to peak at JPY8.1bn (Kowa Co., Ltd. sales) (Ten years following launch; 230,000 patients)

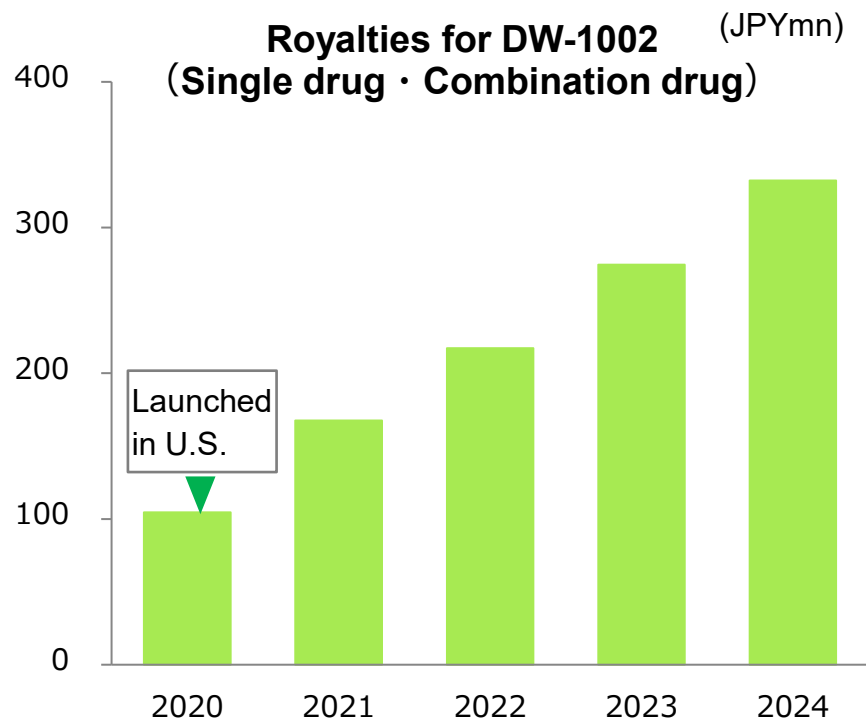
- ✓ GLA-ALPHA® : Growth in royalties in Japan  
December 2024, approval in Thailand
- ✓ GLANATEC® : In Japan, royalty income ended in September 2024.  
⇒ Overall royalties are on the decline

## Japanese Market

- FY2022: about 91.5 billion yen \*
- Use of combination drug is on the rise

Source: Calculated by DWTI based on the 9th NDB Open Data released by Japan's Ministry of Health, Labour and Welfare

# Ophthalmic Surgical Adjuvant DW-1002 (Brilliant Blue G)



Characteristics



Characteristics

✓ **Strong sales, +21.0% YoY increase due to volume increase and yen depreciation**

- Plan to launch Single drug in China and Japan, Combination drug in the U.S.
- ✓ Patents in major countries will expire in December 2025, and US patents have already been extended (until March 2031). After 2026, we expect a decrease in royalties due to the expiration of patents
- ✓ There will be no impact in Japan due to the product supply agreement with exclusive know-how licensing provisions

## ILM-Blue<sup>®</sup>, TissueBlue<sup>™</sup>

Ophthalmic surgical adjuvant with Brilliant Blue G, a dye with excellent staining ability, as the active ingredient

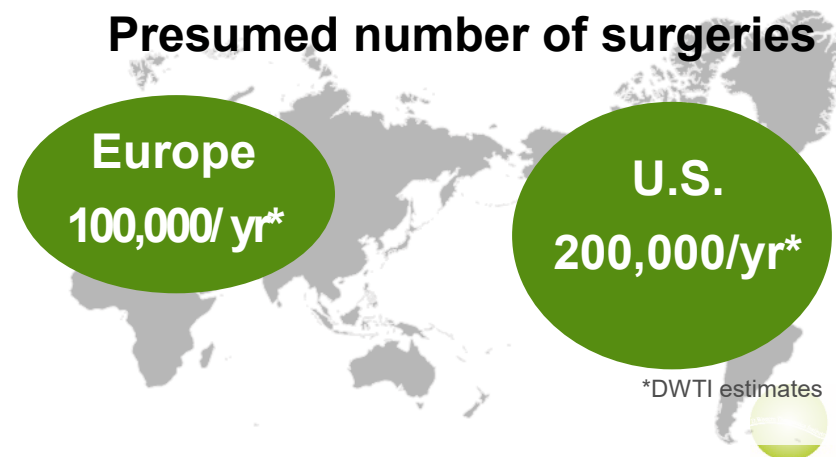
- Enables visualization of the internal limiting membrane (thinness: approx. 0.003mm)
- Used in vitrectomy for the treatment of diabetic retinopathy, macular hole, etc.

## MembraneBlue-Dual<sup>®</sup>

Combination of Brilliant Blue G and Trypan Blue

- Stains internal limiting membrane, epiretinal membrane, and proliferative membrane in proliferative vitreoretinopathy
- Used during vitrectomy, such as proliferative vitreoretinopathy, etc.

### Presumed number of surgeries



\*DWTI estimates



## 2-2. Development Pipeline

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# Development Pipeline

Products		Clinical indication	Region	Non-clinical	P-I	P-II	P-III	Application	Approval	Launch	Licensee
K-321	Ripasudil hydrochloride hydrate	Fuchs endothelial corneal dystrophy	U.S., etc.	▶							Kowa
DW-1002	Brilliant Blue G (BBG)	ILM staining	China	▶							DORC
		ALC staining	Japan	▶							Wakamoto Pharmaceutical
	BBG/ Trypan blue	ILM staining and ERM staining	U.S.	▶							DORC
DW-1001		Ophthalmic treatment agent (undisclosed)	Japan	▶							ROHTO Pharmaceutical
H-1337		Glaucoma and ocular hypertension	U.S.	▶							Developed internally
DW-5LBT		Neuropathic pain after shingles	U.S.	▶							Jointly developed with MEDRx
DWR-2206		Bullous keratopathy	Japan	▶							Joint development with ActualEyes

• • • ophthalmology pipeline

# Fuchs Endothelial Corneal Dystrophy K-321

## → Global Phase III ongoing

Patient registration is taking longer than expected, so the end date has been changed to December 2025  
The application is expected to be submitted at the end of 2026 or in 2027 (our forecast)

Expansion of indications

## Ripasudil hydrochloride hydrate

- ✓ Global Phase III studies commenced in March and April 2023
- ✓ After going on sale, to receive royalties until end of data protection period\*

\*Patent royalty rate differs from that of single agent

## Phase III study

Identifier*	NCT05528172 <b>study completed</b>	NCT05795699	NCT05826353
Summary	Administration to patients after cataract surgery	Administration to patients with FECD after descemetorhexis	Administration to patients with FECD after simultaneous cataract surgery and descemetorhexis
No. of patients	331	100	100
Study period	August 2022–June 2023	March 2023– <b>December 2025</b>	April 2023– <b>October 2025</b>
Development region	U.S.	U.S., Europe, etc.	U.S., Europe, etc.

\*ClinicalTrials.gov Identifier from <https://www.clinicaltrials.gov>

Europe  
Approx. 16mn patients\*1

U.S.  
Approx. 6mn patients\*2

Fuchs endothelial corneal dystrophy (FECD) :  
A progressive condition that causes corneal endothelial disorders, corneal edema and clouding impair vision and lead to bullous keratopathy.

\*1: Obtained by multiplying the population over 40 estimated by the Company based on the United Nations' "World Population Prospects 2022" by the morbidity rate of 4% (\*2)

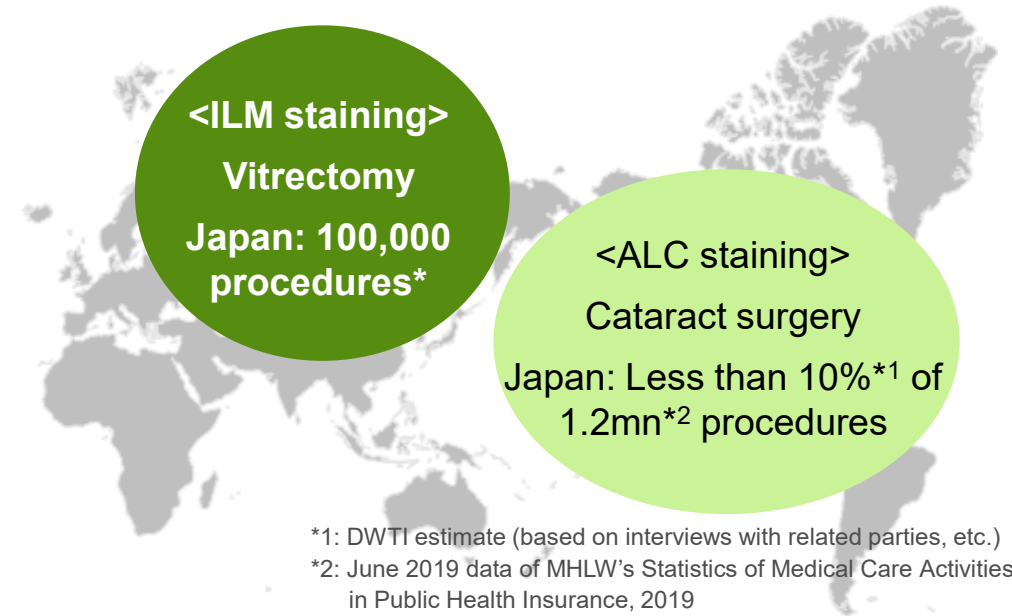
\*2: Moshirfar M et al., Fuchs Endothelial Dystrophy. Treasure Island (FL): StatePearls Publishing; 2021



# Ophthalmic Surgical Adjuvant DW-1002

## → We continue to work towards approval in China, Japan, and the United States

- ✓ China: Marketing application filed in May 2023, treated as a medical device
- ✓ Japan: Issues related to standards and quality in the use of U.S. approved data
- ✓ United States: The FDA has instructed us to conduct a small-scale trial



### Development plan

Clinical indication	Region	Licensee	P-III	Application	Approval	Launch
ILM staining	China	DORC			2025	
ILM staining, ALC staining	Japan	Wakamoto Pharmaceutical(*)		2025	2026	2027
ILM staining and ERM staining	U.S.	DORC		2026	2027	

\*Based on our forecast

# Glaucoma Treatment H-1337 First Choice as Second-Line Drug

➔ The top-line data from the Phase IIb study were favorable, and it was decided to proceed to the Phase III study

- ✓ Patient administration started in August
- ✓ **August 2024: Administration completed**
- ➔ **November: Top-line data results announced**

Internally developed products



Characteristics

- Confirmed safety and efficacy in Phase I/IIa studies (clinical POC obtained,  $p < 0.0001$ )
- Facilitates drainage of aqueous humor through the trabecular meshwork and Schlemm's canal
- Multikinase inhibitor effective on various types of protein kinases

US PI/PIIa results (study period: Mar.-Sep. 2018, 87 cases)

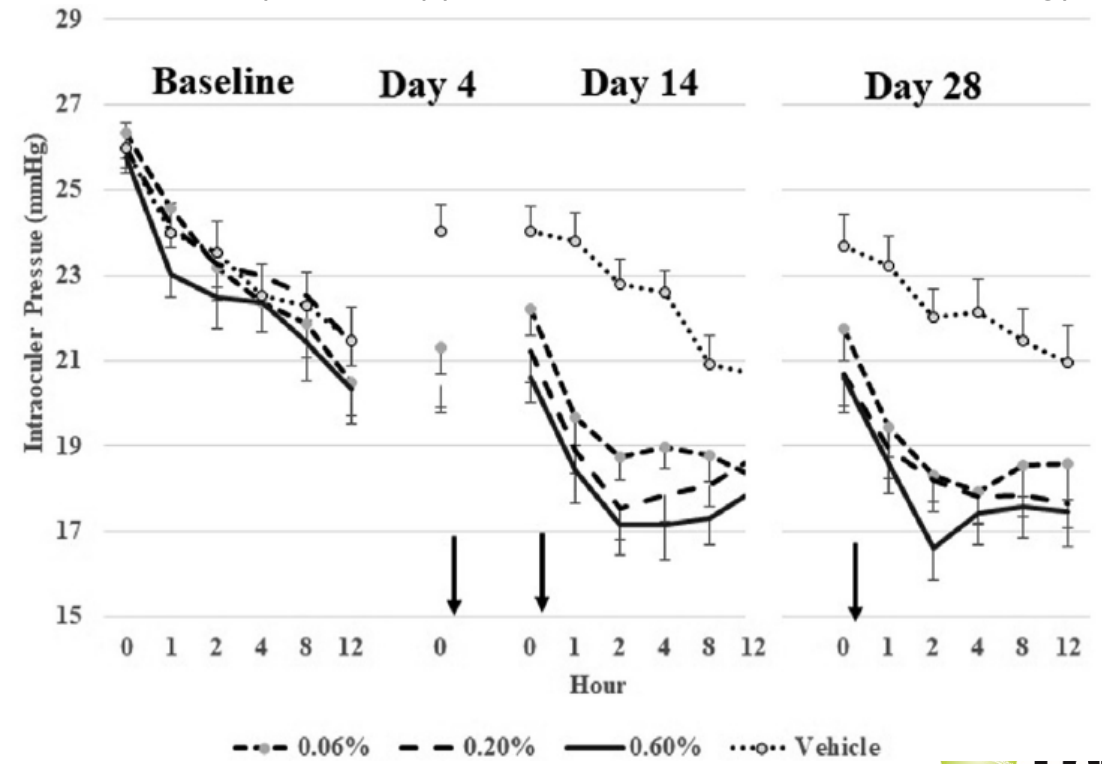
Efficacy

There was a decrease in intraocular pressure in the three groups (0.06%, 0.2%, 0.6%) compared to placebo

Safety

There was sufficient tolerance despite the presence of mild erythema

IOP : Mean ( $\pm$  s.e.m)(intent-to-treat population, mmHg).



# H-1337: Outline of the U.S. Phase IIb Study

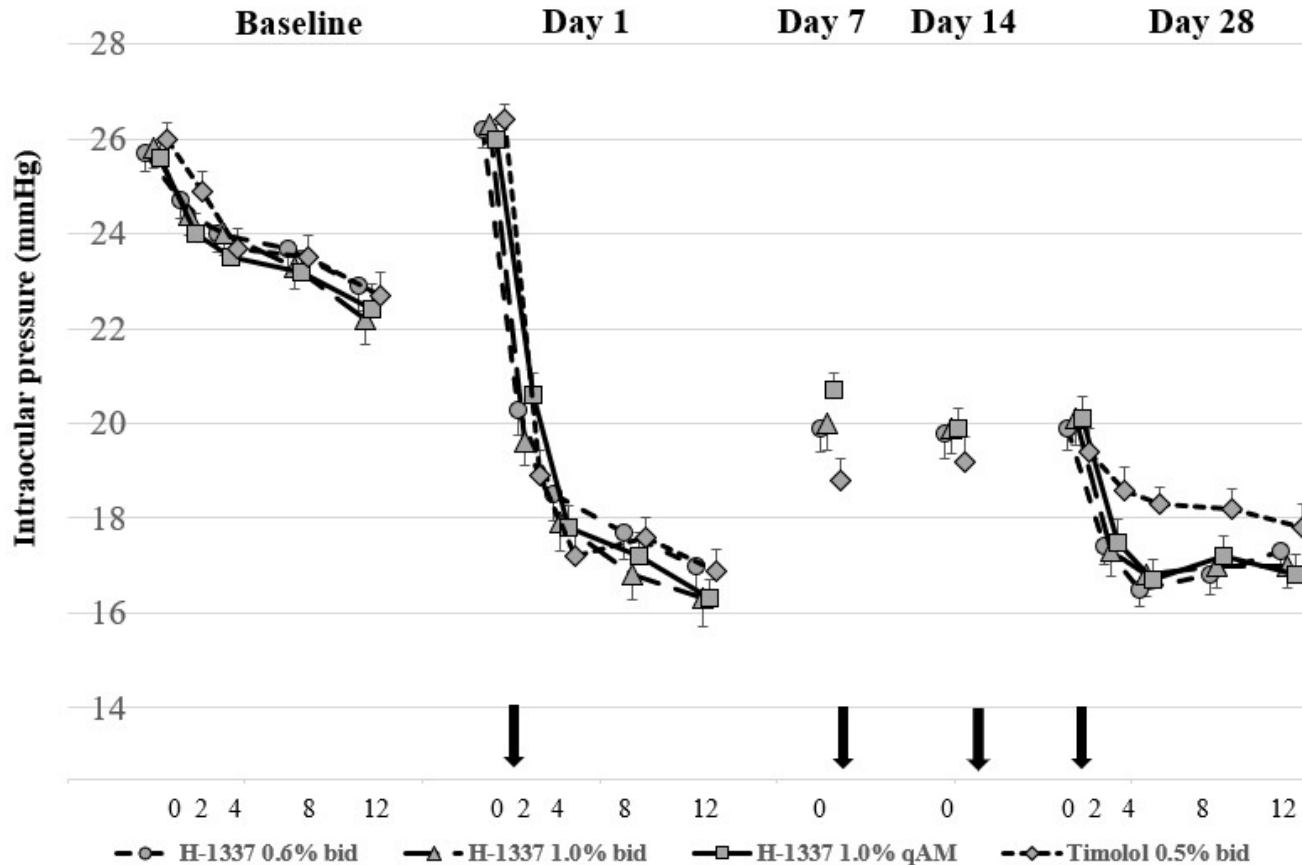
- ✓ The business strategy for this study is as follows
  - The maximum intraocular pressure lowering effect of increasing the concentration
  - The intraocular pressure lowering effect of once-daily instillation
  - The safety of increasing the concentration

Overview	<b>Multi-center, randomized, double-blind, active-controlled, dose-finding study to determine efficacy and safety of H-1337 as a treatment for patients with glaucoma and ocular hypertension</b>				
Dosage and administration	H-1337 (0.6%), H-1337 (1.0%), Timolol: Eye drops administered twice daily H-1337 (1.0%): Eye drops administered once daily				
Number of patients	201	Dosing period	28 days	Mean unmedicated IOP	26mmHg
Primary endpoints	Compare intraocular pressure reduction effect of H-1337 versus Timolol				
Secondary endpoints	Evaluation of ocular and systemic safety				

# Topline Data Results - Announced November 18, 2024

- ✓ Efficacy: All three groups of H-1337 significantly reduced intraocular pressure by up to 30% ( $p < 0.001$ )
- ✓ Safety: Conjunctival hyperemia occurred, but most cases were mild and did not lead to discontinuation of treatment

Mean ( $\pm$  s.e.m) IOP at Baseline and Clinic Visits over 28 days (mmHg)



Efficacy	<ul style="list-style-type: none"> <li>• The range of effects in all three groups was comparable to that of timolol</li> <li>• The results were comparable to those of the PI/IIa study</li> <li>• H-1337 1.0% b.i.d. met statistical non-inferiority for all the post-dose time points on Day 28.</li> </ul>
Safety	<ul style="list-style-type: none"> <li>• Conjunctival hyperemia in about half of cases (temporary effect, characteristic of ROCK inhibitors)</li> <li>• Most cases are mild</li> </ul>

\*Detailed results, etc., are scheduled to be announced at academic conferences and in papers etc. in 2025

# Safety and Toxicity Studies

- ✓ Safety endpoints for the eyes and the whole body were evaluated when H-1337 (1.0%) was administered (September to October 2024)

## 【Purpose】

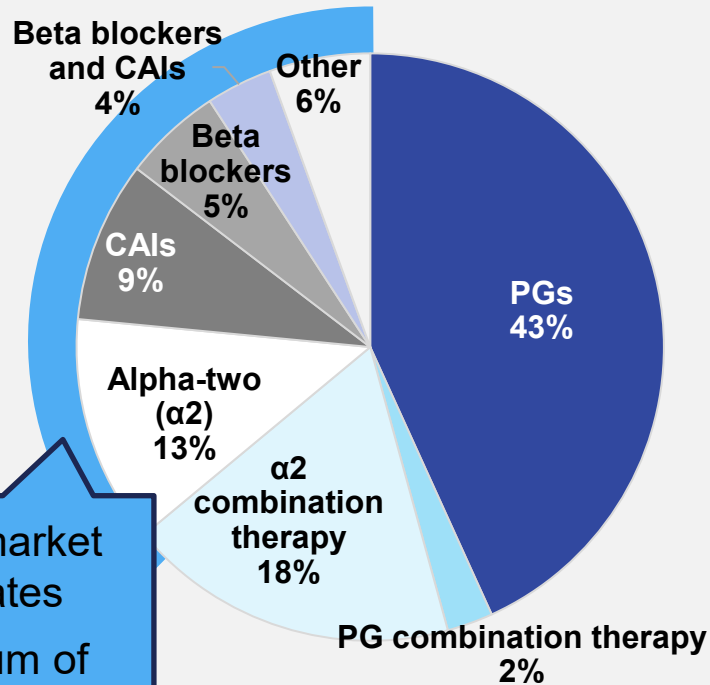
- To confirm systemic exposure to H-1337M1, because the active metabolite H-1337M1 was detected
- To confirm systemic exposure in humans at 1.0%, as the highest dose in P2b was 1.0%

Overview	Safety of the eyes and the whole body is being verified in healthy people		
Dosage and administration	H-1337 (1.0%) : Eye drops administered twice daily		
Number of patients	17	Dosing period	7 days

- ✓ Some of the toxicity tests (non-clinical studies) required at the start of Phase III and before application are currently being conducted

# H-1337 Marketability and Competition

U.S. market (FY2020: about \$3bn) \*1



Target market estimates  
Maximum of 40%  
(\*2)

## 【Evaluation as a second-line drug】

	Number of times eye drops are instilled / decrease in intraocular pressure	Side effect
H-1337 (ROCK inhibitor)	Once daily/ 6~7mmHg	<ul style="list-style-type: none"> <li>Conjunctival hyperemia: 43.4% (Phase 2b: ~4 weeks)</li> <li>Long-term administration side effects unknown</li> </ul>
Ripasudil※3 (ROCK inhibitor)	Twice daily/ ~4mmHg	<ul style="list-style-type: none"> <li>Conjunctival hyperemia: 69%</li> <li>Long-term administration tends to increase the incidence of allergic conjunctivitis and blepharitis</li> </ul>
Netarsudil※4 (ROCK inhibitor)	Once daily/ ~5mmHg	<ul style="list-style-type: none"> <li>Conjunctival hyperemia: 53%</li> <li>Corneal vortex: approx. 20%</li> </ul>
Brimonidine※5 (α2)	3 times daily/ 2~6mmHg	<ul style="list-style-type: none"> <li>Allergic conjunctivitis, conjunctival hyperemia, eye itching: 10~20%</li> </ul>
Brinzolamide ※6 (CAI)	3 times daily/ 4~5mmHg	<ul style="list-style-type: none"> <li>Blurred vision, bitter taste, sour taste: 5~10%</li> </ul>
Timolol (β-blocker)	Twice daily/ 4~5mmHg※7,8	<ul style="list-style-type: none"> <li>Contraindicated for patients with bronchial asthma, systemic side effects (cardiovascular and respiratory systems) ※9</li> </ul>
【FYI : first-line drugs】 Latanoprost※10 (PG)	Once daily/ 6~8mmHg	<ul style="list-style-type: none"> <li>Pigmentation of the iris and periorbital tissues (eyelids), changes in eyelashes</li> <li>Hyperemia: 8%</li> </ul>

※3: Label of GLANATEC®  
 ※4: Label of RHOPRESSA®  
 ※5: Label of ALPHAGAN®

※6: Label of AZOPT®  
 ※7: Ophthalmology 103 : 138-147, 1996.  
 ※8: Arch Ophthalmol 114 : 929-932, 1996.

※9: Label of TIMOPTIC®  
 ※10: Label of XALATAN®

# Outlook, Development

## 【Future considerations】

- ✓ Phase III study: Group composition, dosage and administration
  - Confirmation of timolol non-inferiority
  - Confirmation of long-term safety
- ✓ Consultation with the FDA, preparation for Phase III study (toxicity study)
- ✓ In-house development (fundraising), active licensing out activities

➔ Detailed development plan to be announced as soon as it is finalized

## 【Drug development scenario】

- ✓ Priority on launching in the US market
  - Market: approx. 3 billion dollars (FY2020)
  - Market estimate: up to 40% of the above
  - Aiming for 30 billion yen in sales of the single-agent
- ✓ Pursuit of patient QOL
  - Development of once-daily eye drops
  - Priority on medication compliance
- ✓ Larger-scale products
  - Search for appropriate partners
  - Consideration of product launches in each country and combination products

# Regenerative Cell Therapy DWR-2206

## → Transplantation completed for test subjects, undergoing follow-up observation

- ✓ Mar. 2024: Submission of a clinical trial plan for a domestic Phase II trial
- ✓ Jul. 2024: The first transplant was performed, and progress is going smoothly

→ Dec.: Transplantation completed for test subjects (6 cases)

Scheduled to complete evaluation and observation by the end of Dec. 2025

Joint development product



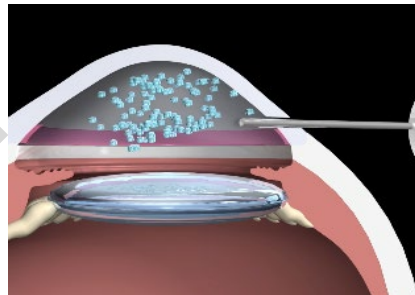
Targeting bullous keratopathy, cultured human corneal endothelial cells and a suspension are injected into the anterior chamber of the eye to regenerate corneal endothelium



Frozen corneal endothelial cell preparation



Warmed to thaw, and injected



Cultured corneal endothelial cells + ROCK inhibitor

## Phase II trial design

Published on jRCT on June 11, 2024 (jRCT2043240040)

### Overview:

- Multi-center, open-label, uncontrolled study to determine the safety and efficacy of DWR-2206 in patients with bullous keratopathy

Target number of patients	6
Evaluation and monitoring period	48 weeks after transplantation of the investigational product
Primary endpoints	Number of cases and incidence rate (%) of adverse events and adverse events that cannot be ruled out as related to the investigational product
Secondary endpoints	<ul style="list-style-type: none"> <li>• Monitoring and evaluation of safety endpoints</li> <li>• Number and incidence rate (%) of significant adverse events</li> <li>• Improvement in visual acuity at 24 weeks after transplantation of the investigational product</li> <li>• Change in best corrected visual acuity over time</li> <li>• Change in corneal thickness over time</li> <li>• Change in corneal endothelial cell density over time</li> </ul>



# DWR-2206 Marketability and Development Plan

## Japan

Number of bullous keratopathy patients estimated 7,000-10,000※1

Patients on waiting list 10,000-20,000※2

Bullous keratopathy :  
The terminal stage of various corneal endothelial disorders, including Fuchs corneal endothelial dystrophy. It can also occur due to damage after cataract and glaucoma surgery.

※1 : source: MHLW ※2 : source: DWTI

## (Reference) Major Competitors of DWR-2206

	Vyznova®
Cell transplantation	Cultured human corneal endothelial cells
Developed by	Aurion Biotech
Development stage	JP: Launch <b>[Drug Price : JPY9,464,500]</b> US: P I / P II

Market Size Forecast (peak : 6th year) \*by Japan's Ministry of Health, Labour and Welfare

- Number of patients using this medical device : 160
- Forecast sales : Approx. JPY1.5bn

## Development Plan

	Non-clinical	P-II		P-III	Application
Japan		2024	2025	2026	2027

- ✓ In Japan, we will conduct clinical trials as usual (without using the early approval system)

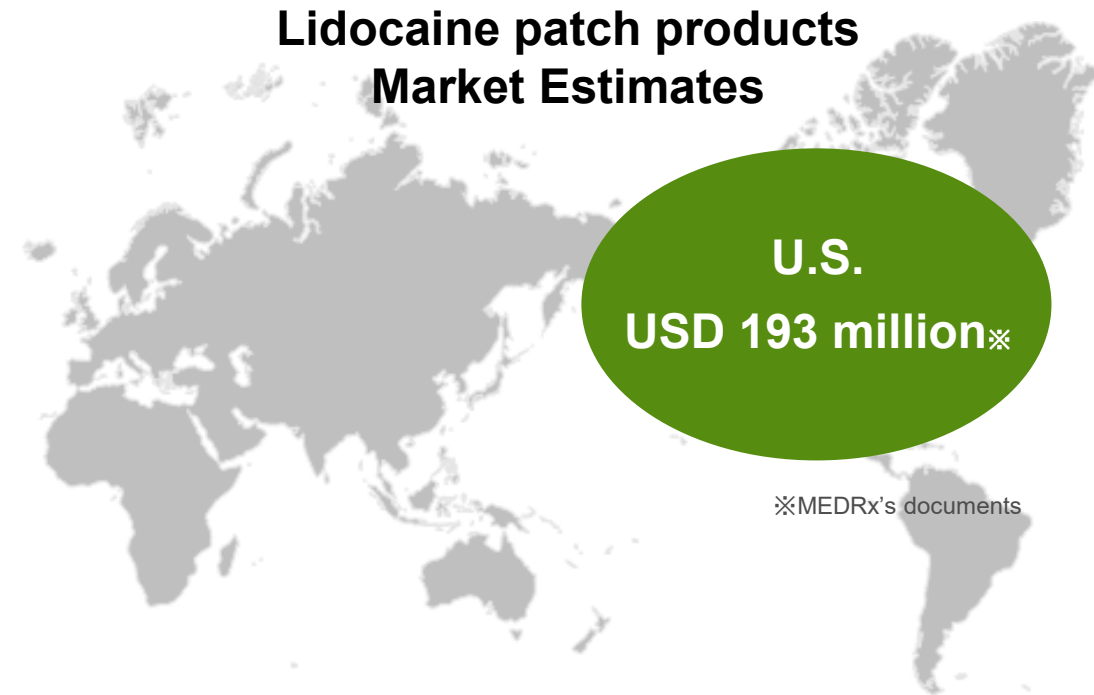
	Clinical Study		
China	2025	2026	2027

- ✓ In China, we plan to begin clinical trials in 2025
- ✓ The leading developer is the Chinese company ArcticVision (a bio-venture)
- ✓ We receive a portion of the revenue (such as milestone revenue) that Actuarize receives

# Neuropathic Pain Treatment DW-5LBT

➔ **Received CRL, analyzing the data for reapplication.**

- ✓ Reapplied in January 2024
- ✓ Received Complete Response Letter (CRL) in July 2024.  
→ Plan to conduct additional analysis and reapply for reapplication.



**Jointly  
Developed**



Lidocaine patch products for a treatment for neuropathic pain after shingles

**Characteristics**

- Confirmatory comparative (bioequivalence) clinical trial comparing DW-5LBT with innovator product Lidoderm® generated favorable results
- Low dermal irritation
- Excellent adhesive strength
- Capable of maintaining adhesive strength during exercise

## 【Development Plan】

	Reapply	Approval	Launch
<b>U.S.</b>	<b>2025</b>		<b>2026</b>

# Joint research results for FY2024 (disclosed)



10/17: Development of a new, innovative eye drop for glaucoma surgery  
Glaucoma surgery can lead to complications after surgery and functional failure over time

Other company

Ophthalmology



11/26: Development of an ED treatment using our company's compounds  
The joint research was extended due to the positive results obtained in animal models

In-house

non-ophthalmology



12/16: Exploratory research aimed at creating a dry eye treatment  
Evaluation of the potential of dry eye treatment drugs using Daiichi Kogyo Seiyaku's compound library

Other company

Ophthalmology



12/25: Joint research on gene therapy drugs for eye diseases  
Evaluation of gene therapy that can be expected to improve visual function in glaucoma

Other company

Ophthalmology



12/27: Joint research on cancer treatment drugs using our compounds  
Focusing on new therapeutic target factors, evaluation of efficiency endpoints for cancer

In-house

non-ophthalmology



2025/1/28: Joint research on treatment drugs for eye diseases  
Evaluate the efficiency endpoints of our compounds for retinal degenerative diseases and ocular inflammatory diseases

In-house

Ophthalmology

# 3. FY12/25 Forecast

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# Medium-term Management Plan (2020-2024)

## Management themes

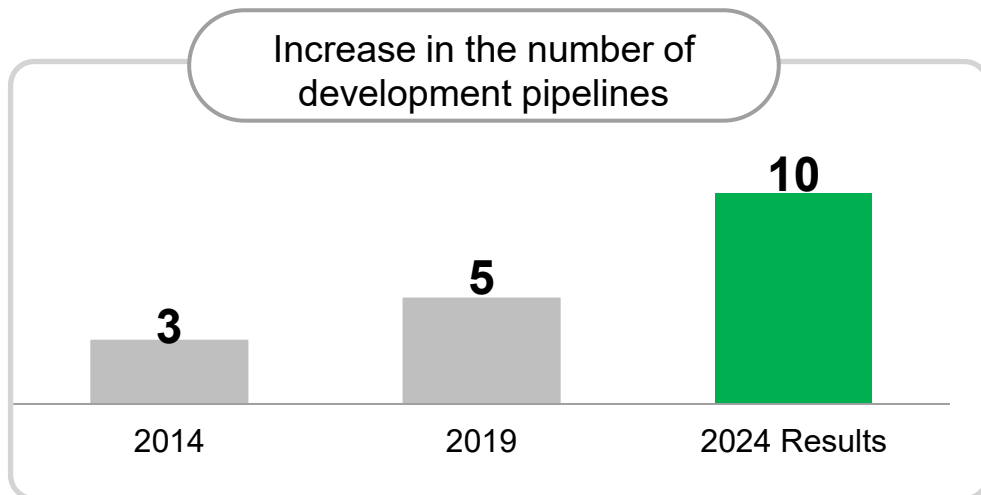
Enhancement of development pipeline and  
Expansion of business domain

## Medium-term management plan (2020–2024)

Increase number of pipeline products and  
undertake later-stage clinical development

## indicator

Increase in the number of units in the  
development pipeline : 10 by the end of 2024



## Results over the past five years

### Enhancement of development pipeline

- ◎ Increase in products launched and products co-developed
- ◎ Upgrading of products already licensed out

### Expansion of business domain

- ◎ Promotion of in-house development of H-1337 for Phase IIb study in the US
- ◎ Implementation of joint development of DWR-2206 and DW-5LBT

# Future Initiatives: Our Vision and Three Growth Drivers



## Innovative New Drugs to the World from Japan

### POINT 01

**Ophthalmic  
diseases**

~Providing Optimal Treatment~



### POINT 02

**Core Technologies**

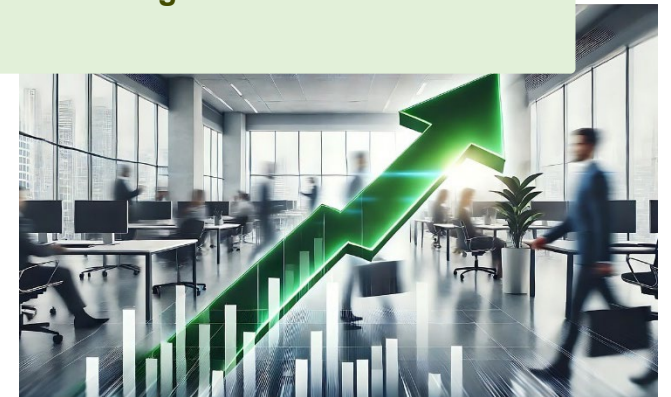
~Deepening and Expanding~



### POINT 03

**Marketability**

~Strategic Market Selection~



## <Policy for initiatives>

- Maximize the value of our know-how by leveraging our three growth drivers
  - Provide optimal therapeutic modalities (incorporate new modalities)
  - Utilization of core technologies
  - Ophthalmology unmet medical needs

	Ophthalmology	Non-ophthalmological
<b>Kinase inhibitors or products using in-house technology</b>	 	 
<b>New modality or other company's product</b>	   	<p>*Multiple other joint research projects are underway</p>

# Consolidated Earnings Forecast for FY12/25 (released February 10, 2025)

(JPYmn)

	FY12/24	FY12/25		Primary factors
	FY results	FY forecast	YoY change	
<b>Net sales</b>	471	400	(71)	<ul style="list-style-type: none"> <li>• Mainly, royalty income from DW-1002 and GLA-ALPHA</li> <li>• Milestone income from DW-1002(Japan) is expected</li> <li>• A decrease in revenue is expected due to the end of domestic royalties for GLANATEC</li> </ul>
<b>Operating loss</b>	(1,209)	(670)	539	<ul style="list-style-type: none"> <li>• Research and development expenses decreased due to the completion of administration of H-1337 and DWR-2206</li> <li>• Other SG&amp;A expenses were generally in line with the previous year</li> </ul>
<b>Ordinary loss</b>	(1,228)	(680)	548	
<b>Loss attributable to owners of parent</b>	(1,290)	(680)	610	
<b>R&amp;D expenses</b>	1,367	760	(607)	<ul style="list-style-type: none"> <li>• Main breakdown               <ul style="list-style-type: none"> <li>- Development expenses for H-1337 Phase III study (toxicity tests, investigational drug manufacturing, etc.)</li> <li>- Research expenses for new drug development (in-house drug discovery and joint research) increased YoY</li> </ul> </li> </ul>

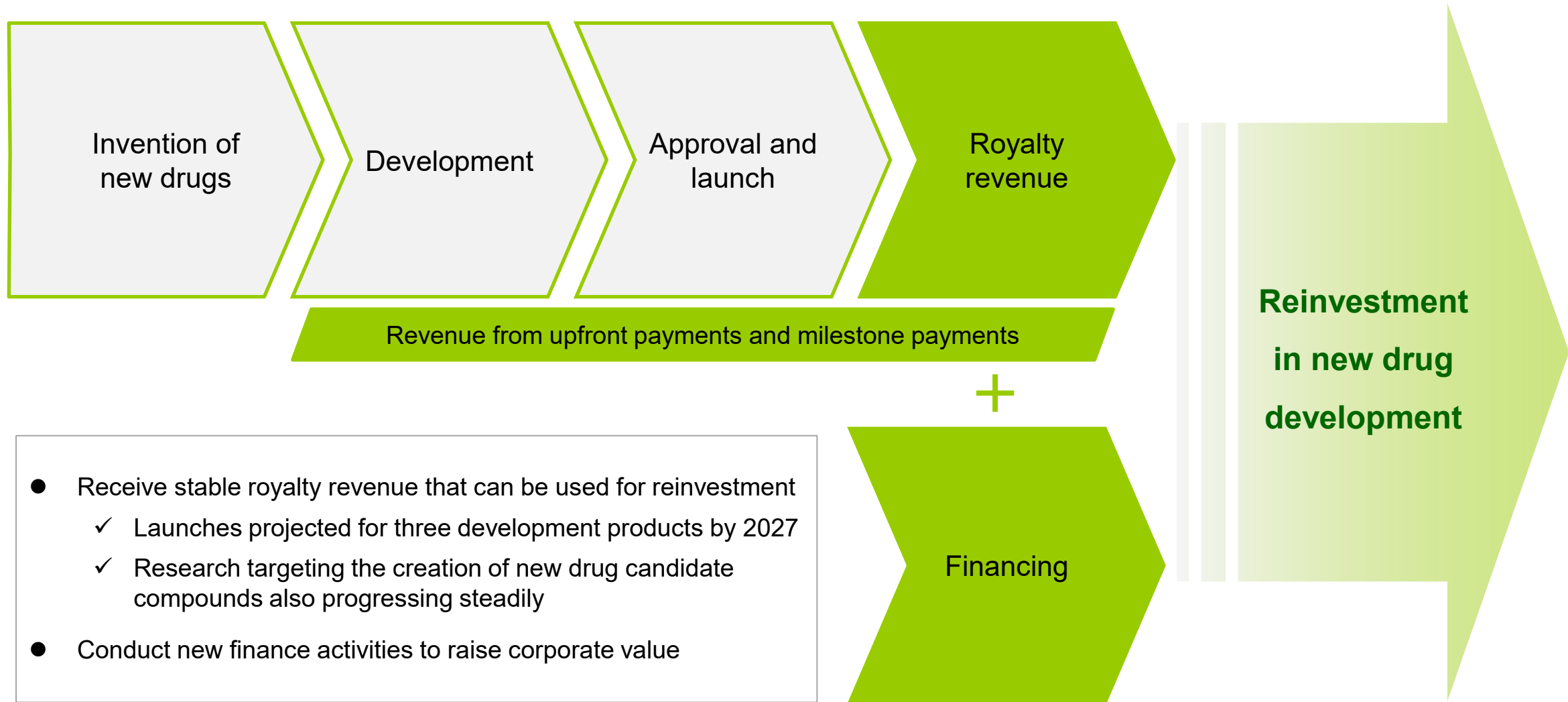


# Development Pipeline Plan

Products and Clinical indication		Region	2024	2025	2026	2027
H-1337	Glaucoma and ocular hypertension	U.S.	P2b	P3 Preparation and licensing out activities		
K-321	Fuchs endothelial corneal dystrophy	U.S.	P3	Application *2026 or later		
DW-5LBT	Neuropathic pain after shingles	U.S.	Re-application	Approval	Launch	
DW-1001	Ophthalmic treatment agent	Japan	To be determined		*Due to the policy of the licensing out company, Rohto Pharmaceutical, we are currently considering future development plans	
DW-1002	ILM staining	China	Application	Approval	Launch	
	ILM staining ALC staining	Japan	Application		Approval	Launch
	ILM staining and ERM staining	U.S.	Application preparation		Application	Approval → Launch
DWR-2206	Bullous Keratopathy	Japan	Nonclinical	P2	P3	Application
		China	Clinical trial planned for 2025			

Note: Development plans are based on development plans of the licensees or our forecast. Hence, actual development progress may differ from that plan.

# Our Ongoing Growth Cycle



# Borrowings and Financing Status

## Borrowings

Balance (as of Dec. 31, 2024)	Credit limit	Use of funds	Type
JPY90mn	JPY200mn	Funds for the milestone payment for neuropathic pain treatment DW-5LBT	Term loan contract with commitment period
JPY405mn	JPY440mn	Funds for the development of regenerative cell therapy DWR-2206	Term loan contract with commitment period

- ✓ Completion of repayment of DW-1002 funds

## Other financing

Total amount (Exercise completed on February 7, 2025)	Use of funds	Type
JPY1,145mn	<ul style="list-style-type: none"> <li>• Development funds for “H-1337”</li> <li>• Expenses related to drug discovery research activities (including joint research) and the acquisition and development of new pipelines</li> <li>• Funds for the redemption of corporate bonds (first unsecured convertible corporate bonds with stock acquisition rights)</li> <li>• Working capital</li> </ul>	Series 12 Stock Acquisition Rights


## Future funding needs

- ✓ Funds for the next stage of development for H-1337
- ✓ Funds for the development of newly discovered and/or acquired pipeline products

# **(Reference) Business Overview**

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# DWTI Overview / History

Name	D. Western Therapeutics Institute, Inc. (DWTI)
Markets	Tokyo Stock Exchange Growth Market (Code : 4576)
Business	New drug discovery, research, and development
Capital	JPY1.2bn
Officers and Employees	32 (connection)
Location	Head office : Nagoya-shi, Aichi, Japan R&D laboratory : Tsu-shi, Mie, Japan (Established Institute of Human Research Promotion and Drug Development at Mie University)
Consolidated Subsidiary	Japan Innovative Therapeutics, Inc.  <b>Japan Innovative Therapeutics</b>

Focus on basic research

Expansion of business domain  
-Undertaking internally development  
-Collaboration with other companies

- 1999 Founded of a company
- 2006 Established R&D laboratory (Mie University)
- 2009 Listed on Tokyo Stock Exchange Growth Market
- 2014 Launch in Japan of internally developed products 
- 2015 Started of In-licensed products developed by other companies
- 2018 Started of internally clinical development
- 2022 Started of jointly development of regenerative medicine products

As of December 31, 2024

# Business Highlights

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- Four products available on the market
- Five products in late stages of development (Phase III study or later)

1,500

- About 1,500 kinase inhibitors included in DWTI's compound library
- A pioneer in the field of kinase inhibitors

7

- Out-licensed seven products
- Internally developing Three additional products (including joint development)

## Our Businesses

Drug Discovery	Internal drug discovery	<ul style="list-style-type: none"> <li>✓ Create promising kinase inhibitors from our original compound library with efficiency</li> <li>✓ Create new drug seeds by collaborating with other companies</li> </ul>
	Clinical development	<ul style="list-style-type: none"> <li>✓ Internal clinical development (including the evaluation of safety and efficacy in humans)</li> </ul>
Drug Development	Business development	<ul style="list-style-type: none"> <li>✓ Out-licensing activities for original products and in-licensed products</li> <li>✓ Consider in-licensing of products in late development stages and repurposed drugs</li> </ul>

# Core Technologies to Create New Drugs

- ◆ DWTI's drug discovery engine is an original core technology that enables us to continuously create new drugs
- ◆ A kinase is an enzyme that phosphorylates proteins; excessive phosphorylation is a factor that contributes to the onset of various diseases (kinases regulate protein activity)

## Drug discovery engine

### Compound library

- ✓ Superior new drug seeds
- ✓ Includes three launched drugs

### Drug design

- ✓ Ability to create new drugs from compounds in our library (experience, data)

### Drug-Western Method

- ✓ Tool for exploring mechanisms of action of new drugs
- ✓ Enhance value by estimating mechanisms (estimate safety and elements of therapeutic effects)

## Potential uses of kinase inhibitors

### Various indications

- ✓ Kinases play a critical role in a variety of diseases
- ✓ Kinase inhibitors are primarily used in anti-cancer agents; development of kinase inhibitors to treat immune, neurodegenerative, and inflammatory diseases is also under consideration

### Large market scale

- ✓ Total annual sales of kinase inhibitors exceed JPY2tn

### DWTI is a pioneer in the field of kinase inhibitors

- ✓ Launched in 1995, fasudil is the world's first kinase inhibitor (and is included in our compound library)



# Innovative New Drugs to the World from Japan

D. Western Therapeutics Institute



- These materials have been created with the goal of facilitating understanding regarding the company and were not produced for the purpose of soliciting investment in the company.
- Earnings forecasts and projections regarding future events included within these materials are based on determinations made by the company using information that was available at the time at which these materials were produced and are therefore subject to impact from potential risks and uncertainties. Consequently, actual results may differ significantly from these forecasts and projections due to a variety of factors, including changes in business environment.
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D. Western Therapeutics Institute, Inc.

