D.WESTERN THERAPEUTICS INSTITUTE

Q2 FY12/24

Financial Results Briefing Materials

August 9, 2024

D. Western Therapeutics Institute, Inc.

Stock Code: 4576

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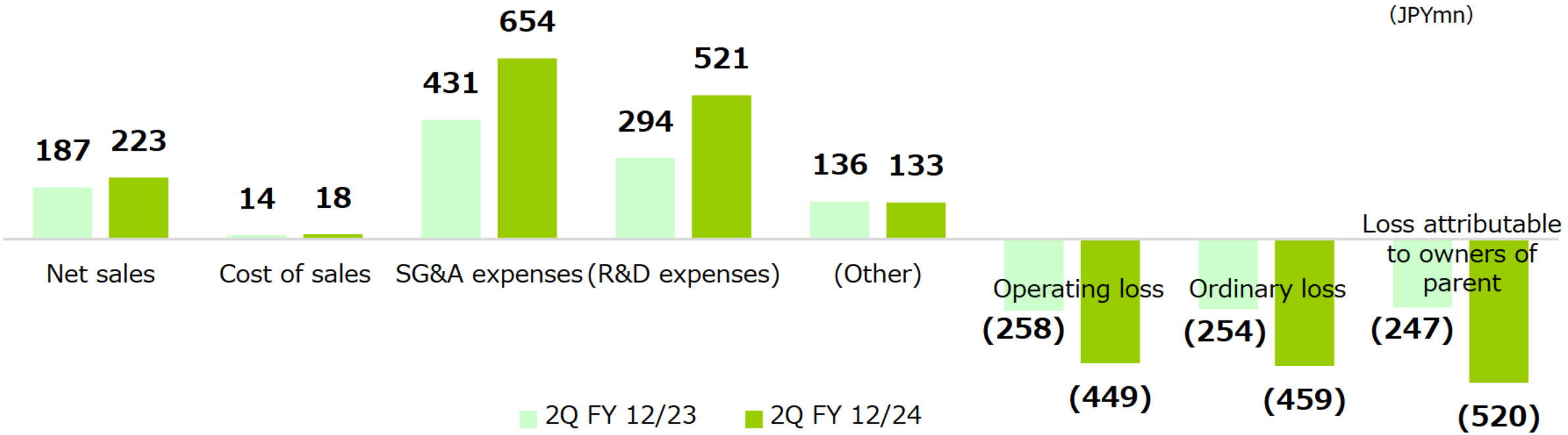
1. Q2 FY12/24 Financial Results

January 1 – June 30, 2024

DWTI

Consolidated Statement of Income（YoY comparison）



Net sales

- Net sales were up 19.1% YoY, due to strong royalties
- Royalties for GLANATEC® declined, but royalties for GLA-ALPHA® grew steadily, royalties for GLANATEC FAMILY rose 13.3% YoY. Royalties for DW-1002 rose 20.4% YoY, due to the yen depreciation.

R&D expenses

- R&D expenses rose 76.9% YoY due to increased spending on development of H-1337 (Phase IIb study in the U.S.) and DWR-2206.

DWTI

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

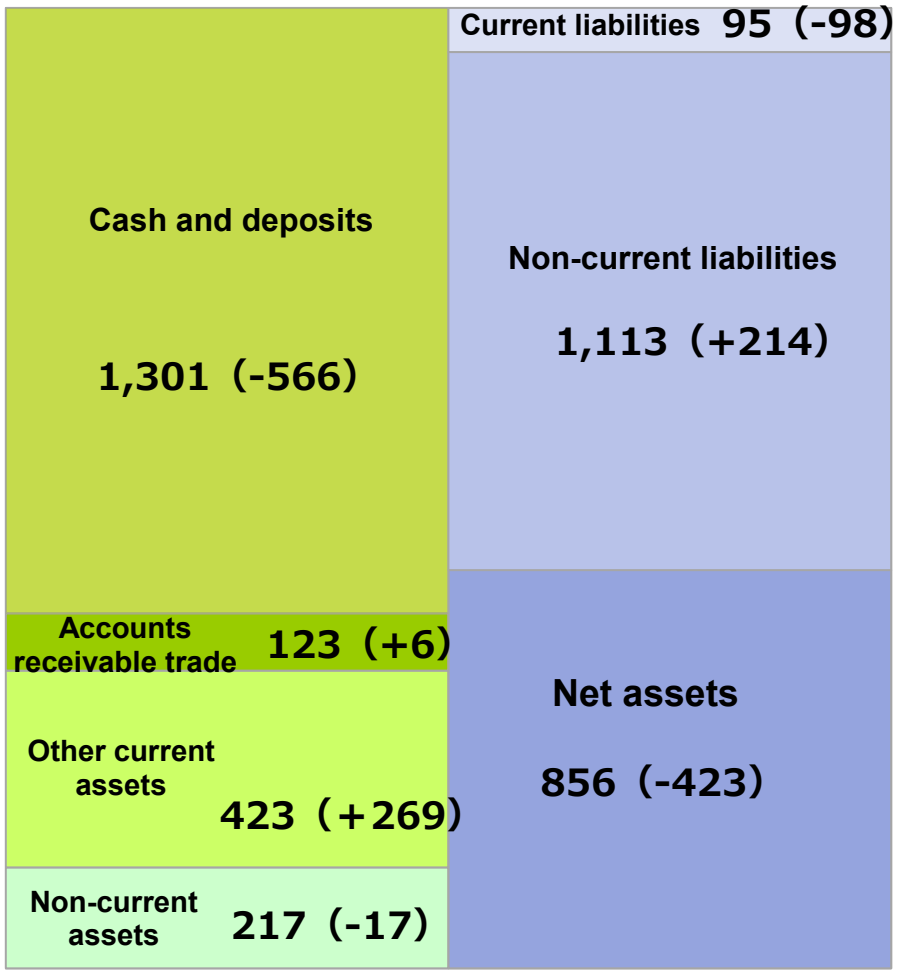
(JPYmn)

	FY 12/23		FY 12/24				
	1H results	FY results	1H results	YOY change	FY forecast (out Feb.13)	Progress	Primary factors
Net sales	**187**	**428**	**223**	**35**	**400**	**55.9%**	• Storong royalties for DW-1002 and GLANATEC FAMILY
SG&A expenses	431	1,190	654	223			
R&D expenses	294	930	521	226	1,600	32.6%	• Development expenses for H-1337 was less than expected. It will be expensed upon completion
Other SG&A expenses	136	259	133	(3)			
Operating loss	**(258)**	**(798)**	**(449)**	**(191)**	**(1,500)**	**–**	
Ordinary loss	**(254)**	**(796)**	**(459)**	**(204)**	**(1,510)**	**–**	
Loss attributable to owners of parent for the interim period	**(247)**	**(812)**	**(520)**	**(272)**	**(1,510)**	**–**	• Loss on redemption of convertible bonds of JPY60mn in extraordinary losses

Consolidated Statement of Income

As of June 30, 2024
(change compared to December 31, 2023)

(JPYmn)



Cash and deposits

- Declined due mainly to R&D expenditures
- Funding for immediate business development activities is secured., supported in part by the exercise of Series 12 Stock Acquisition Rights

Supplies

- JPY260mn increase in advance payments to suppliers due to H-1337 development

Non-current assets

- JPY20mn in amortization of intangible assets related to the licensing agreement for DW-1002 (Europe)

Current liabilities

- JPY112mn 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

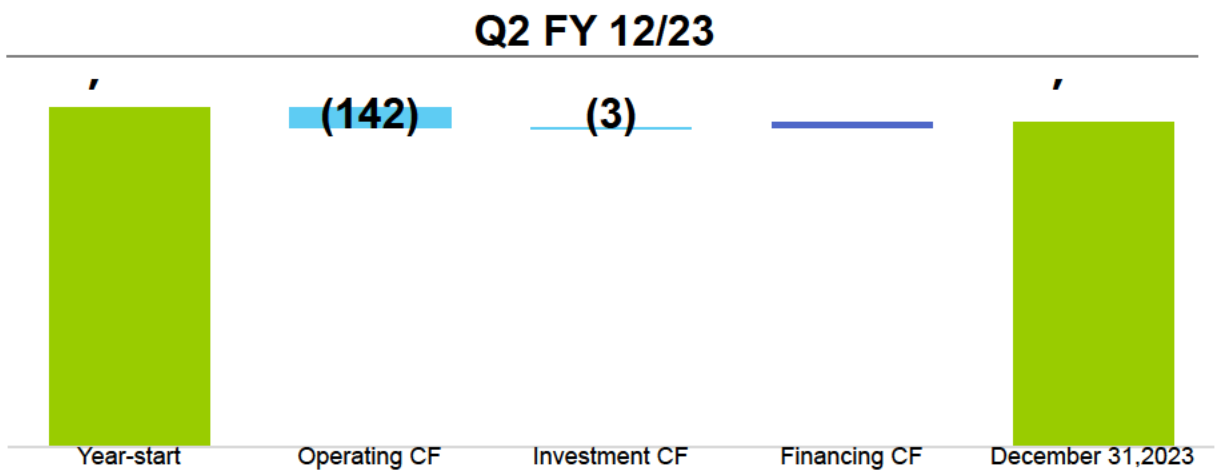
- JPY160mn increase in long-term borrowings due to loans to fund the development of DWR-2206
- JPY53mn increase due to difference between issuance of bonds payable of JPY660mn and redemption of convertible bonds of JPY60mn

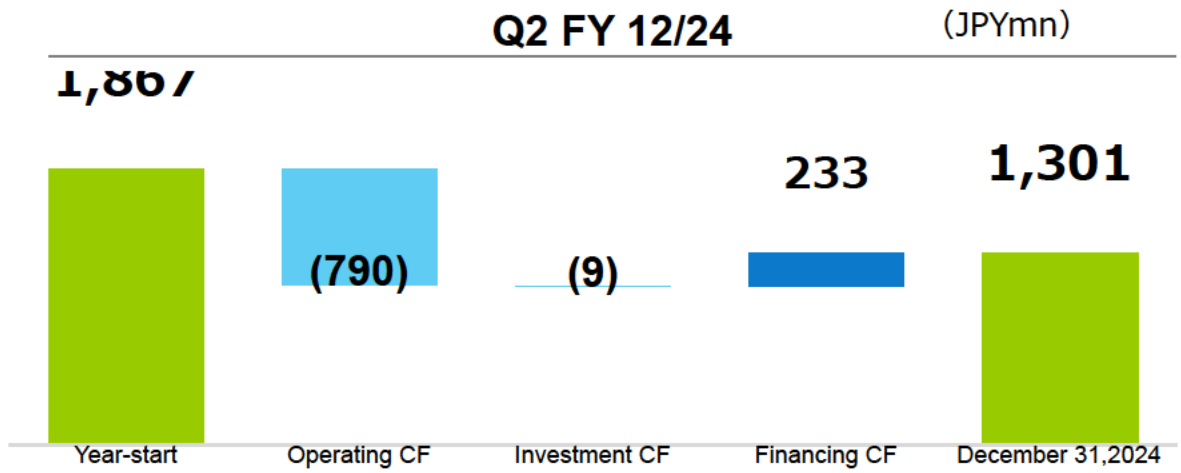
Net assets

- Recorded a loss attributable to owners of parent of JPY520mn
- Recorded JPY45mn each in capital and capital reserves due to exercise of stock acquisition rights

DWTI

Consolidated Cash Flow Statement





Cash flow from operating activities

- JPY519mn outflow due to the recording of loss before income taxes, JPY260mn due to increase in advance payments to suppliers

Cash flow from investing activities

- JPY8mn outflow from acquisition of property, plant and equipment

Cash flow from financing activities

- JPY660mn proceeds from issuance of bonds, JPY170mn proceeds from long-term borrowings, JPY65mn proceeds from the exercise of stock acquisition rights
- JPY666mn redemption of convertible bonds

On-hand liquidity on June 30, 2024 consisted only of JPY1.3bn in cash and deposits (no securities)

【Exercise status of Series 12 Stock Acquisition Rights】

- ✓ Number of shares exercised 900,000（6.9%）
- ✓ Total amount raised JPY80mn

(As of June 30, 2024)

Issuance of Unsecured Corporate Bonds (Private Placement) and Series 12 Stock Acquisition Rights (Announced on May 17, 2024)

Series 1 Convertible Bonds
JPY606mn

Series 11 Stock Acquisition Rights
13,990 units remaining
(1.3mn shares)

Total funds raised
JPY1.0bn

Corporate Bonds
JPY660mn

Series 12 Stock Acquisition Rights
13mn new shares
(dilution ratio: 40%)

Total funds to be raised
JPY1.4bn

- ✓ Redeem convertible bonds with funds raised from corporate bonds
- ✓ Cancel Series 11 Stock Acquisition Rights and issue Series 12 Stock Acquisition Rights
- ✓ Change from fixed to variable exercise price to facilitate fundraising
- ✓ Cantor, the allottee, will sell the company shares to foreign institutional investors off-market, hence the sales will have little impact on the share price
- ✓ No stock lending
- ✓ Funds raised as of July 31, 2024: JPY313mn (ratio of stock acquisition rights exercised: 29.2%)

【Use of funds for Series 12 Stock Acquisition Rights

Specific use of funds	Amount (JPYmn)	Expected timing of expenditure
① **Development funds for H-1337**	400	March 2025–December 2027
② **Funds for drug discovery research (including joint research) and acquisition of new pipelines/ funds for promoting development**	200	October 2024–December 2027
③ **Bond redemption funds (Series 1 Unsecured Convertible Bonds with Stock Acquisition Rights)**	660	7 June 2024
④ **Working capital**	167	January 2025–December 2027

2. Progress of Business in FY12/24

Development Pipeline in 2024 1H

products on market	Region	Current state
GLANATEC® (Single drug)	Japan, Asia	Decrease slightly due to launch of compounded drugs
GLA-ALPHA® (Combination drug)	Japan	Launched in December 2022, Strong sales
DW-1002 (Single drug)	Europe, U.S.	Strong due to yen depreciation
DW-1002 (Combination drug)	Europe, etc.	Strong due to yen depreciation

Products		Region	Non-clinical	P-I	P-II	P-III	Application	Approval	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.							Phase IIb ongoing
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

2-1. Successful launch (commercialization)

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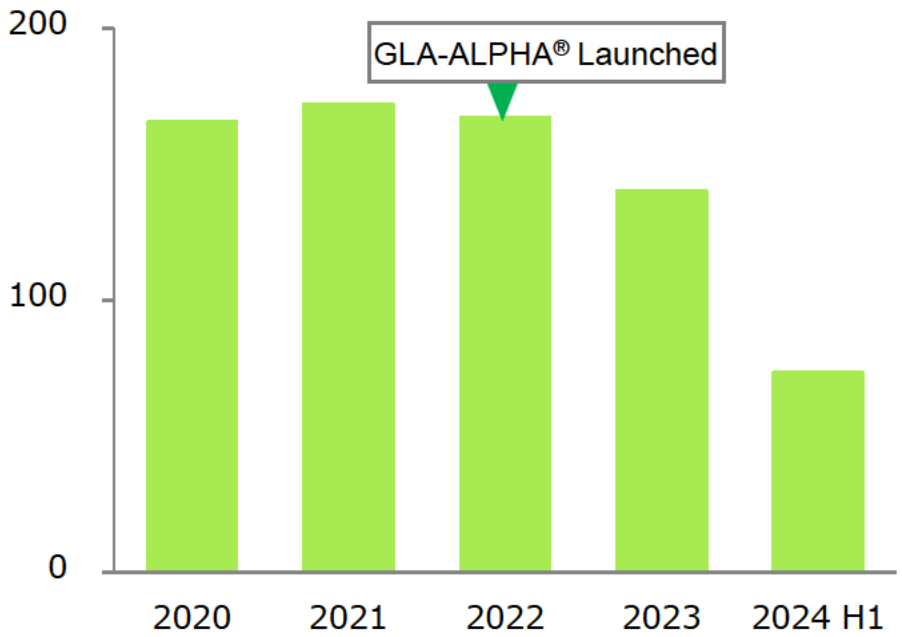
Glaucoma Treatment Ripasudil hydrochloride hydrate

(JPYmn)

Royalties for GLANATEC FAMILY
(Single drug・Combination drug)



GLANATEC® Ophthalmic Solution 0.4%

- ✓ The company expects to receive royalties for the single agent for up to 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**(Filed in Thailand in December 2023 and in Singapore in February 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®, steady progress to date
- ✓ GLANATEC® royalties are scheduled to end in September 2024.
  ⇒Overall royalties are on the decline

Japanese Market

- FY2021: about 80.8 billion yen
- Use of combination drug is on the rise

Source: Calculated by DWTI based on the 8th NDB Open Data released by Japan's Ministry of Health, Labour and Welfare

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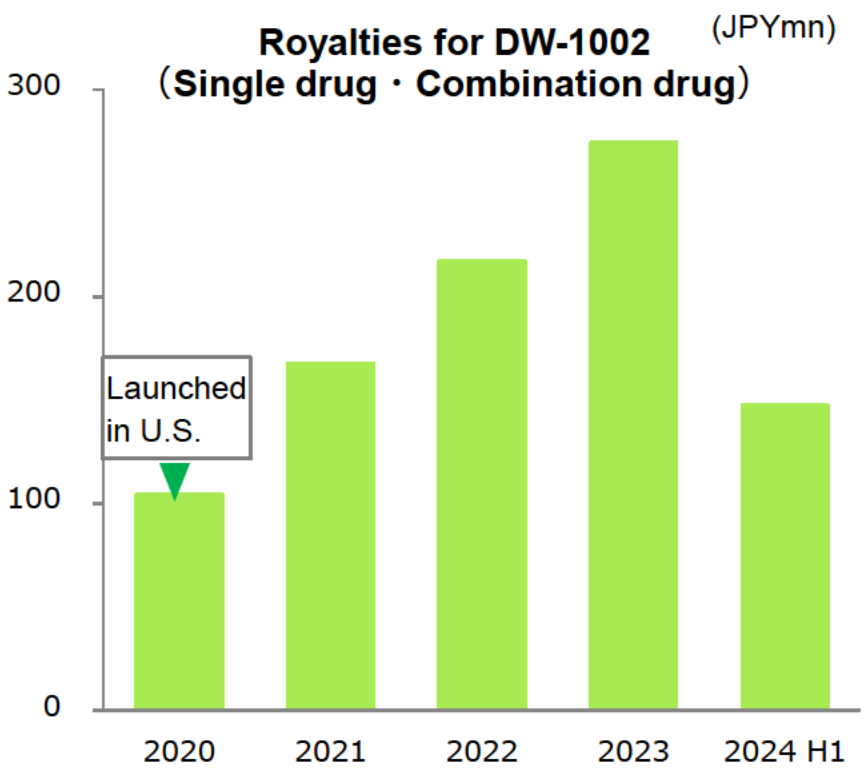
Ophthalmic Surgical Adjuvant DW-1002 (Brilliant Blue G)



Charact eristics

ILM-Blue®, TissueBlue™

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.

Charact eristics

MembraneBlue-Dual®

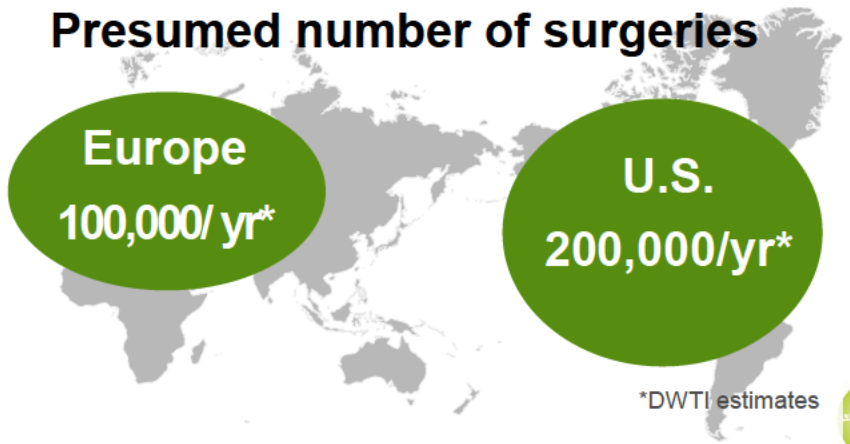
Combination of Brilliant Blue G and Trypan Blue

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

✓ **Strong sales**
+20.4% YoY change increase due to yen depreciation

✓ Plan to launch Single drug in China and Japan, Combination drug in the U.S.
Expects a substantial increase in royalties

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
			Japan								Wakamoto Pharmaceutical
		ALC staining	Japan								
	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

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Fuchs Endothelial Corneal Dystrophy　K-321

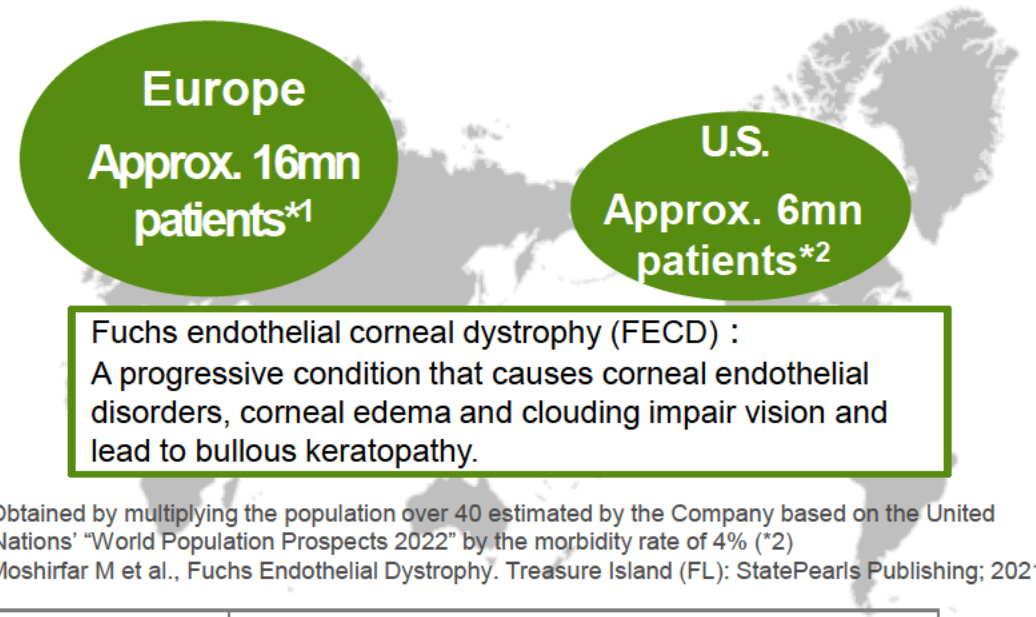
➔Global Phase III ongoing

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



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

Phase III study

Identifier*	NCT05528172 **study completed**	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–January 2025	April 2023–January 2025
Development region	U.S.	U.S., Europe, etc.	U.S., Europe, etc.

*ClinicalTrials.gov Identifier from https://www.clinicaltrials.gov

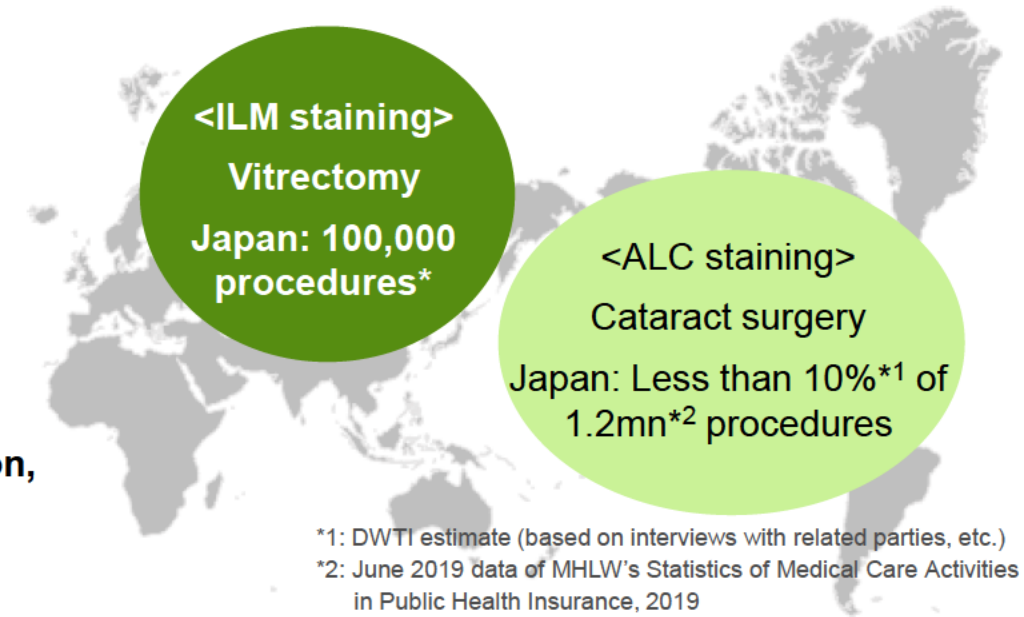
Ophthalmic Surgical Adjuvant DW-1002

➔Consultation with PMDA ongoing toward marketing application submission

Single drug **China, Japan**

- ✓ 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

⇒**Aiming to apply in FY2024, but depending on the status of consideration, the development plan may be affected.**



*1: DWTI estimate (based on interviews with related parties, etc.)
*2: June 2019 data of MHLW's Statistics of Medical Care Activities in Public Health Insurance, 2019

Combination drug **U.S.**

- ✓ Obtained orphan drug designation from the U.S. FDA in July 2023. Preparing for application.

Development plan

Clinical indication	Region	Licensee	P-III	Application	Approval	Launch
ILM staining	**China**	DORC		**2023**	**2024**	
ILM staining, ALC staining	**Japan**	Wakamoto Pharmaceutical(*)		**2024**	**2025**	
ILM staining and ERM staining	**U.S.**	DORC		**2025**	**2026**	

*Based on our forecast

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

➔Phase IIb study ongoing in U.S.

Internally developed products

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Charact eristics

- 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

【State of Progress 】

- ✓ Patient administration started in August
- ✓ No change in plan, although it took time to patient inclusion
- ✓ No new recruitment planned; patient registration largely complete

➔Top line data to be released in late 2024.

Phase IIb trial design

Overview:

- 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.

Planned number of patients	200
Dosing period	28 days
Dosage and administration	H-1337 (0.6%), H-1337 (1.0%) Timolol: Eye drops administered twice a day H-1337 (1.0%): Eye drops administered once a day
Primary endpoints	Compare intraocular pressure reduction effect of H-1337 versus Timolol
Secondary endpoints	Evaluation of ocular and systemic safety

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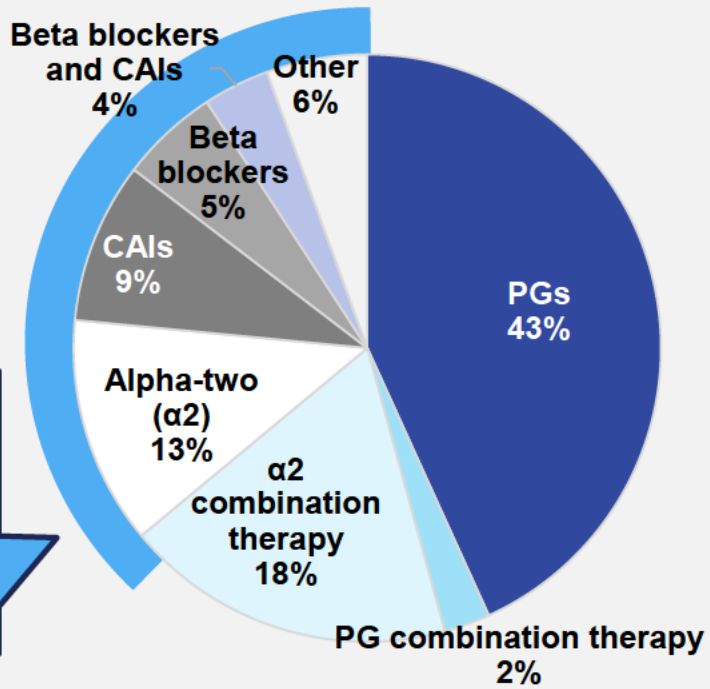
H-1337 Marketability and Development Plan

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



Target market estimates

Maximum of 40% (*2)

*1 :Classified and compiled by DWTI based on IQVIA MIDAS Dec 2020 MAT Reprinted with permission
*2 : Calculated by DWTI based on Journal of Managed Care & Specialty Pharmacy, Vol. 25, No. 9 September 2019, 1001-1014

Standard treatments for glaucoma

- Prostaglandin analogues (PGs) demonstrate the strongest IOP-lowering effect among first-line drugs; generic drugs are available and are most frequently used
- PGs also have little to no effect on many patients, and more than half of drug-treated patients use multiple medications

➔ **Needs for new drugs that are different in action from PGs, and have sufficient efficacy and high safety**

【Development Plan】

	P-I/IIa	P-IIb		P-III
U.S.		**2023**	**2024**	**2025** or later

- ✓ **Toxicity studies required at the start of PIII are being conducted to start a smooth start of PIII**
- ✓ PIII policy (in-house development or out-licensing) is under consideration

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Regenerative Cell Therapy DWR-2206

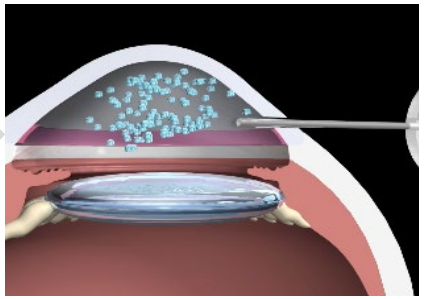
➔ Submitted a Clinical Trial plan Notification for Phase II in Japan

Joint development product ActualEyes

Targeting bullous keratopathy, cultured human corneal endothelial cells and a suspension containing ROCK inhibitor 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

【State of Progress 】

✓ **Submitted a Clinical Trial plan Notification in March**

→Preparations underway, including patient screening

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	・Monitoring and evaluation of safety endpoints ・Number and incidence rate (%) of significant adverse events ・Improvement in visual acuity at 24 weeks after transplantation of the investigational product ・Change in best corrected visual acuity over time ・Change in corneal thickness over time ・Change in corneal endothelial cell density over time

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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

Reason why new treatment is sought

Only treatment for bullous keratopathy is a corneal transplant, which has the following challenges.

- Donor shortage
- Highly skilled surgeon and sophisticated equipment required for surgery
- Risks include infection, astigmatism, rise in intraocular pressure, and adhesion failure of transplant.

Development Plan

	Non-clinical	P-II		P-III
Japan	2023	2024	2025	2026

✓ The rights for Greater China and Korea have already been licensed to Arctic Vision by the originating company, ActualeEyes

(Reference) Competitors of DWR-2206

	Vyznova®	EO2002	CLS001
Cell transplantation	Cultured human corneal endothelial cells	Magnetic nanoparticle-loaded cultured human corneal endothelial cells	iPS cell-derived human corneal endothelial cells as an alternative to donor corneal endothelium
Developed by	Aurion (U.S.)/CorneaGen Japan	Emmecell (U.S.)	Cellusion
Development stage	Japan : Approval U.S. : Phase I / Phase II	U.S. : Phase I	Global : Phase I

Neuropathic Pain Treatment DW-5LBT

➔Received CRL, analyzing the data for reapplication.

Jointly Developed

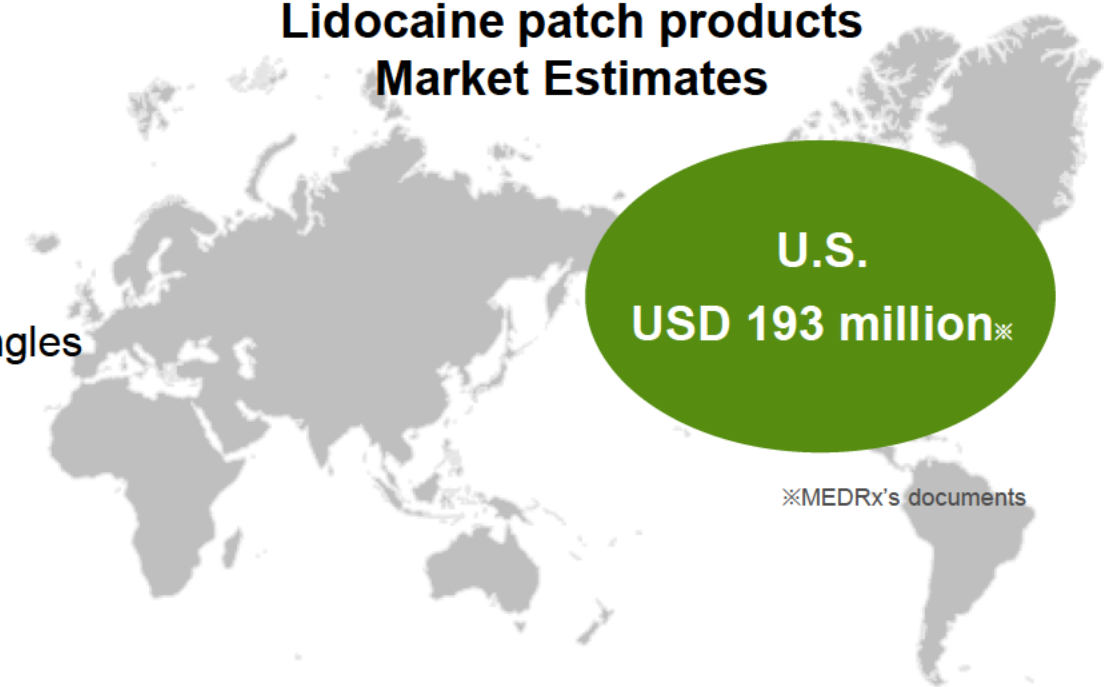
MEDRx

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

Lidocaine patch products Market Estimates



※MEDRx's documents

【State of Progress 】

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

【Development Plan】

	Reapply	Approval	Launch
U.S.	**2024**		

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3. FY12/24 Forecast

Initiatives in 2024, the final year of the medium-term management plan

Management themes

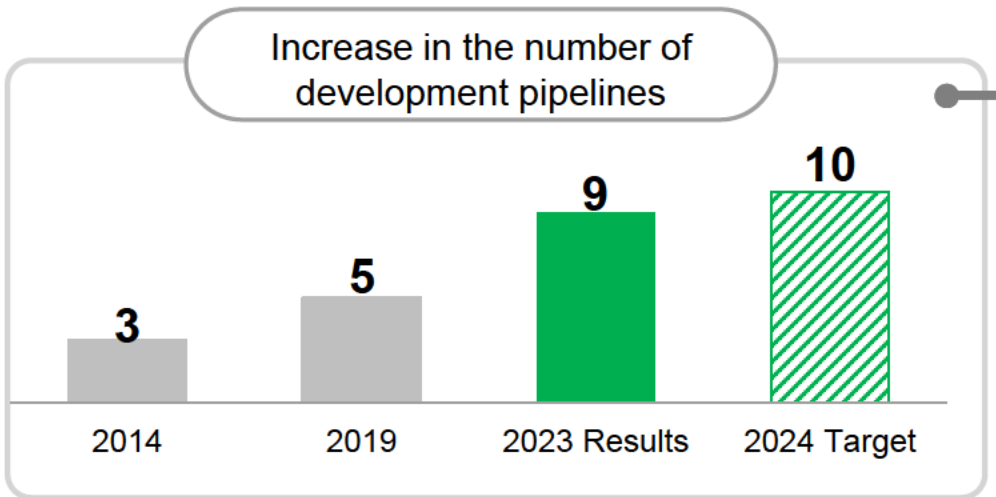
Enhancement of development pipeline and
Expansion of business domain

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



Initiatives in 2024

Enhancement of development pipeline

- Increase due to the start of clinical trials for DWR-2206
- Support development of pipeline products in later stage of development
- Take in-house drug discovery and collaborative drug discovery to the next level

Expansion of business domain

- Promote development (Phase IIb study in US) of H-1337

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2024 Event Calendar

H-1337	Publish top-line data of Phase IIb study in US
DW-5LBT	U.S. reapplication ～ Approval, Launch ✕ Received CRL
DWR-2206	Start of Phase II study in Japan ✓ **achieved** achieved in March
DW-1002	Application, approval and Launch in China, Application in Japan
New projects	Research progress (including new collaborations)

DWTI

Consolidated Earnings Forecast for FY12/24 (released February 9, 2024)

(JPYmn)

	FY12/23	FY12/24		
	FY results	FY forecast	YoY change	Primary factors
Net sales	428	400	(28)	• Royalty income from GLANATEC® will end, but sales of DW-1002 are expected to increase. • The main breakdown is as follows. - Royalty income: DW-1002 (Europe, US, China, etc.), GLANATEC®, GLA-ALPHA® - Milestone revenue: DW-1002 (Japan)
Operating loss	(798)	(1,500)	(702)	• Increase in R&D expenses • Other SG&A expenses are expected to be approximately the same as the previous year.
Ordinary loss	(796)	(1,510)	(714)	
Loss attributable to owners of parent	(812)	(1,510)	(698)	
R&D expenses	930	1,600	670	• Increase expenses to prepare for Phase Ⅲ clinical trials of H-1337 in the U.S. • Increase expenses for R&D activities to create new drugs(In-house drug discovery and collaborative research).

Fund procurement through the issue of stock acquisition rights ongoing (until June 3, 2027)

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Development Pipeline Plan

Products and Clinical indication		Region	2023	2024	2025	2026
H-1337	Glaucoma and ocular hypertension	U.S.	P2b		P3	*2025 or later
K-321	Fuchs endothelial corneal dystrophy	U.S.	P3			Application
DW-5LBT	Neuropathic pain after shingles	U.S.		Re-application / Approval		Launch
DW-1001	Ophthalmic treatment agent	Japan		P2		
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

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

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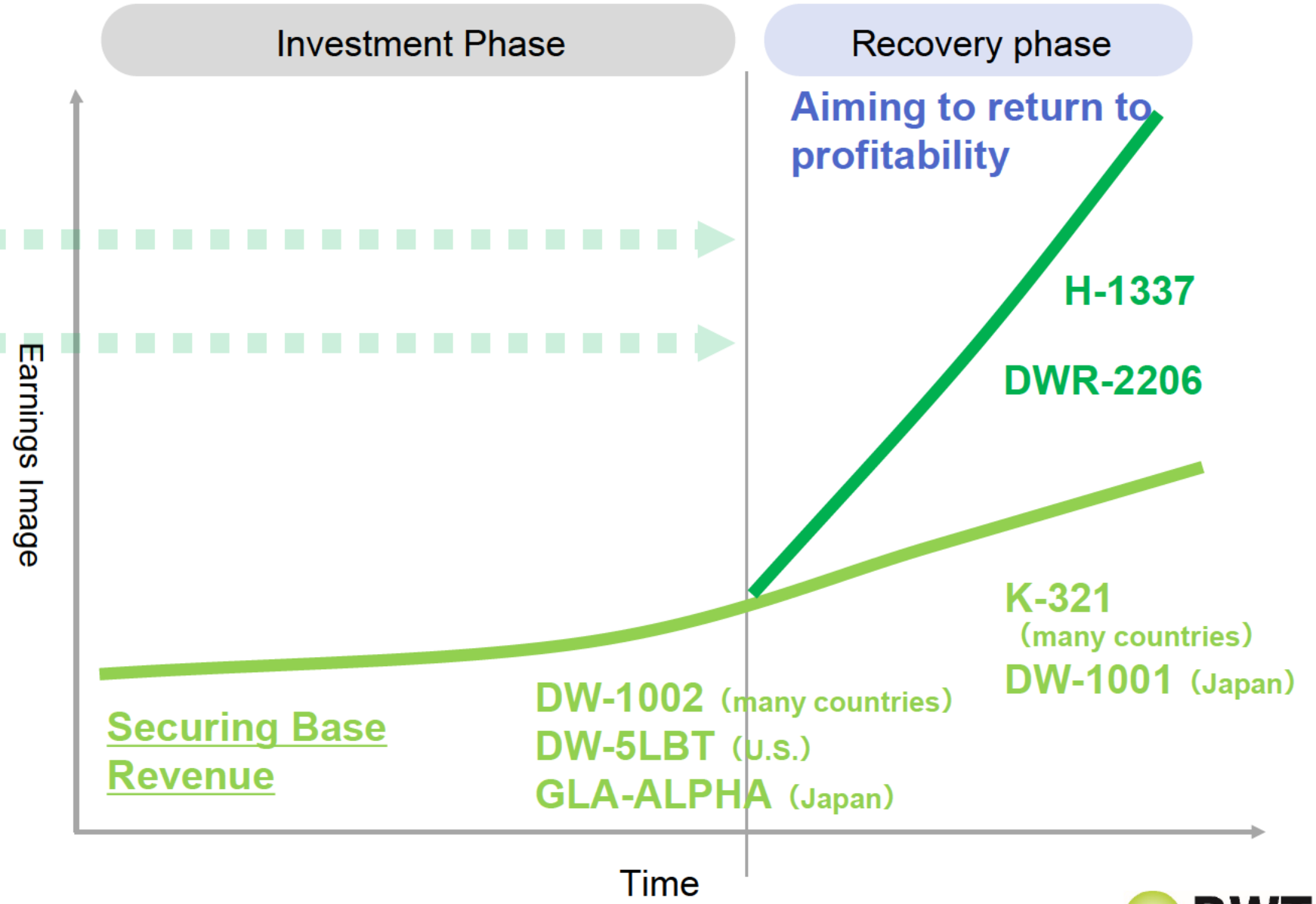
Investment in Growth and Securing Base Revenue

Growth-oriented investment	H-1337 DWR-2206
Base Revenue	Products on Market Licensed-out developed products



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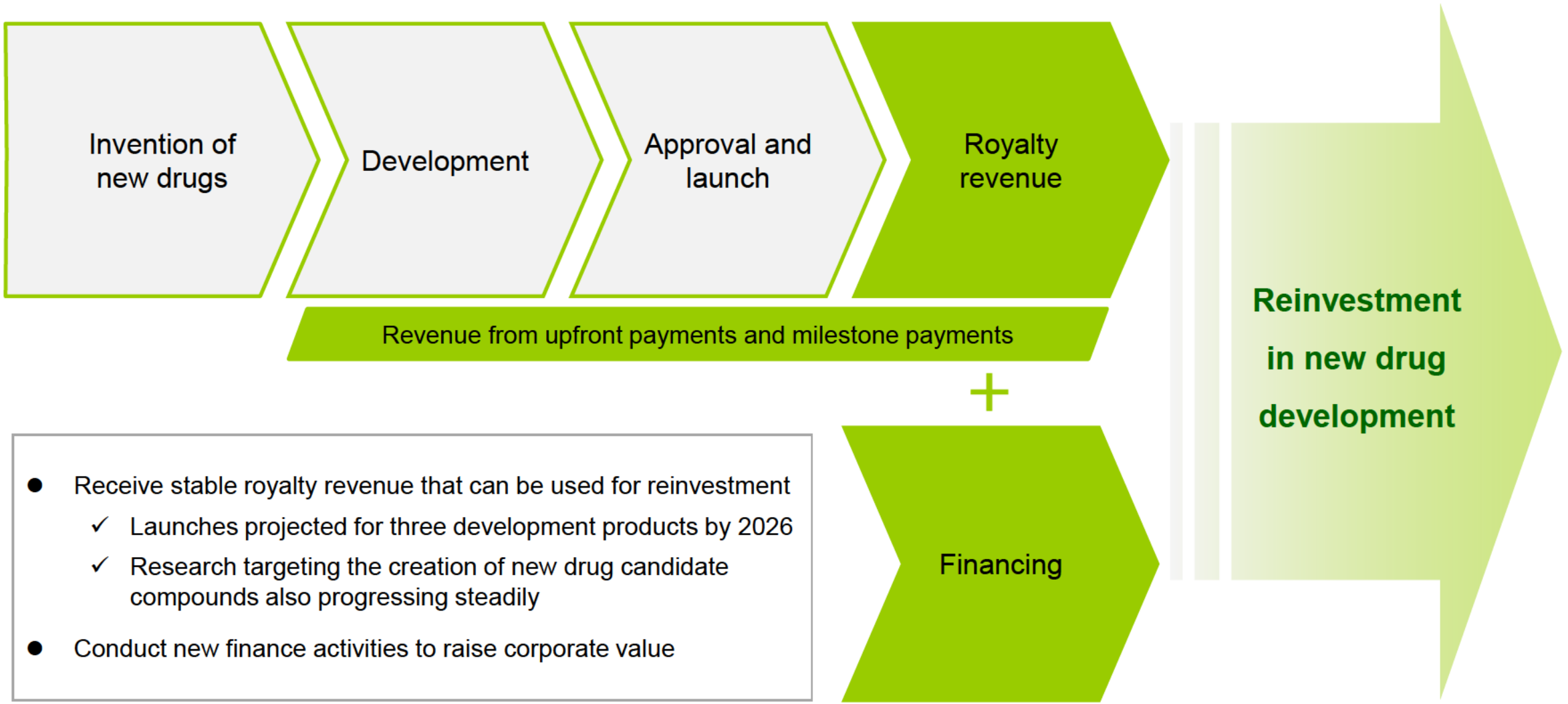
Our Ongoing Growth Cycle



- Receive stable royalty revenue that can be used for reinvestment
  - ✓ Launches projected for three development products by 2026
  - ✓ Research targeting the creation of new drug candidate compounds also progressing steadily
- Conduct new finance activities to raise corporate value

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(Reference) Business Overview

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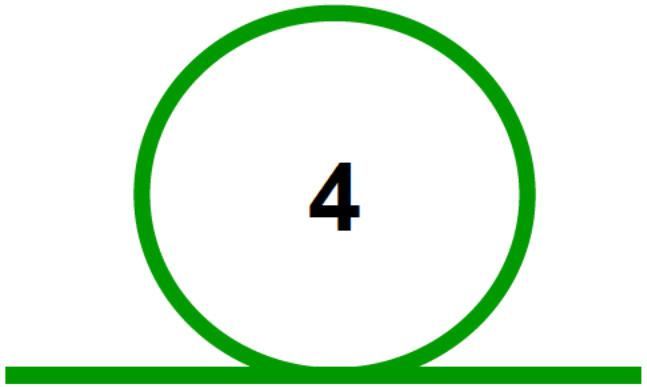
DWTI Overview / History

Name	D. Western Therapeutics Institute, Inc. (DWTI)
Markets	Tokyo Stock Exchange Growth Market (Code : 4576)
Business	New drug discovery, research, and development
Capital	JPY877mn
Officers and Employees	33 (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.

Focus on basic research	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
Expansion of business domain -Undertaking internally development -Collaboration with other companies	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

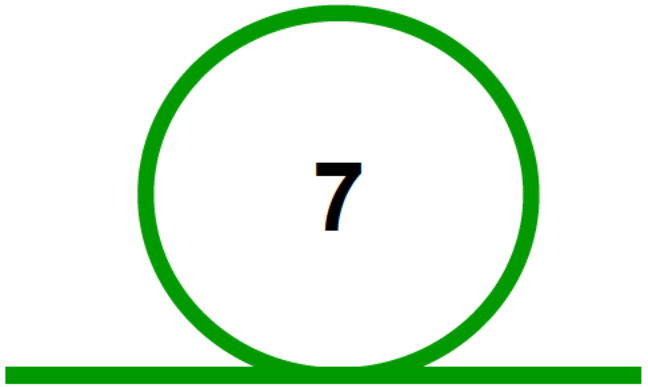
As of June 30, 2024

Business Highlights



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

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



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

Our Businesses

Drug Discovery	Internal drug discovery	✓ Create promising kinase inhibitors from our original compound library with efficiency ✓ Create new drug seeds by collaborating with other companies
Drug Development	Clinical development	✓ Internal clinical development (including the evaluation of safety and efficacy in humans)
	Business development	✓ Out-licensing activities for original products and in-licensed products ✓ Consider in-licensing of products in late development stages and repurposed drugs

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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

DWTI

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- 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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