# Financial Results Briefing for the First Six Months of the Fiscal Year Ending December 2024

August 2, 2024 Torii Pharmaceutical Co., Ltd.

- Financial Results for Q2 2024
- Revised Financial Forecasts for 2024
- Business Update
- Status of Corporate Governance
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# Financial Results for Q2 2024

■ Despite an increase in cost of sales, both net sales and operating income before R&D expenses experienced strong growth

		vs. Q2 2023		
(Millions of yen)	Q2 2024	Increase/ decrease	Pct. change	
Net sales	28,309	+2,610	+10.2%	
Gross profit	12,607	+678	+5.7%	
Operating income	3,141	+1,630	+107.9%	
Operating income before R&D expenses*	4,504	+580	+14.8%	
Net income	2,221	+1,134	+104.4%	
(Reference) R&D expenses	1,363	-1,050	-43.5%	

<sup>\*</sup> We are actively investing in R&D for the time being, in order to obtain in-licensed drugs in the future. For this reason, we have set operating income before R&D expenses as a numerical income indicator for the Medium-Term Management Plan.

#### **Net sales**

 Double-digit year-on-year growth continued to be driven by the skin disease and allergens areas

#### **Operating income**

- Cost of sales increased, but profit also increased due to increased net sales
- R&D expenses are significantly lower compared to the same quarter of 2023, due to a one-time payment (approx. 1.6 billion yen) for in-licensed drugs from Nogra Pharma Limited made in that quarter

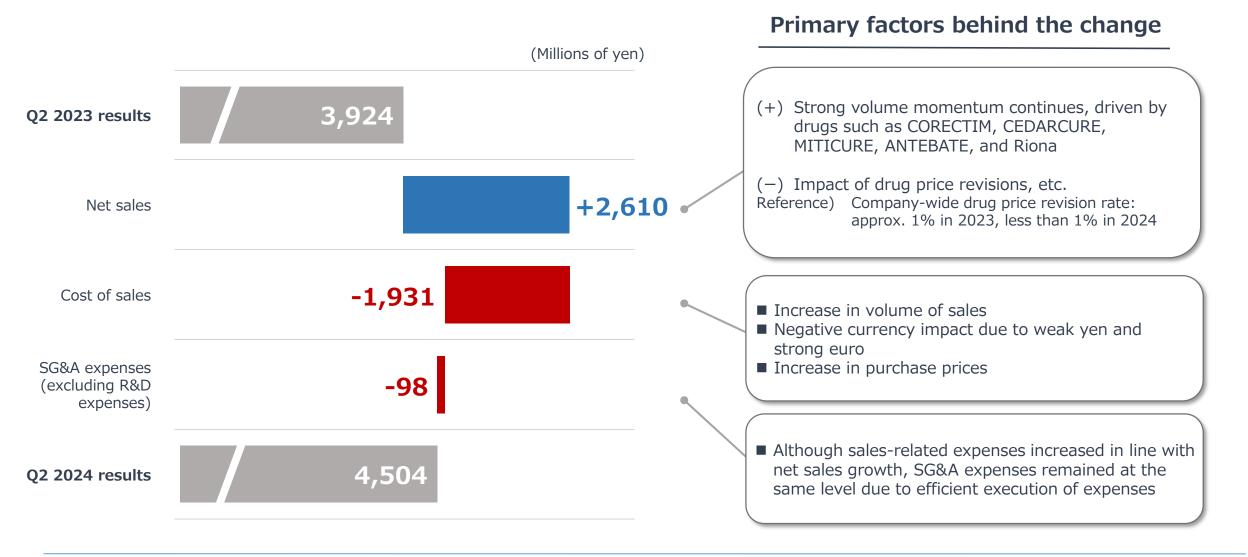
#### Operating income before R&D expenses

Cost of sales increased, but profit also increased due to increased net sales

#### **Net income**

 Profit rose due to increased operating income despite an increase in corporate tax and non-operating expenses

# Factors behind Change in Operating Income before R&D Expenses



# Net Sales - Renal Disease and Hemodialysis, Skin Disease

# Renal disease and hemodialysis

	02 2024	vs. Q2	2023
(Millions of yen)	Q2 2024	Increase/decrease	Pct. change
Net sales - Renal disease and hemodialysis	5,444	-181	-3.2%
- Riona	3,789	+296	+8.5%
- REMITCH	883	-483	-35.4%
- Other	771	+4	+0.6%

#### Riona

 Revenue increased due to higher sales volume from the widespread use of prescriptions for iron deficiency anemia, offsetting the negative impact of NHI drug price revisions

#### **REMITCH**

 Revenue decreased as a result of lower sales volume from the impact of generic drugs and the negative impact of NHI drug price revisions

#### **Skin disease**

	02 2024	vs. Q2 2023		
(Millions of yen)	Q2 2024	Increase/decrease	Pct. change	
Net sales - Skin disease	8,225	+1,348	+19.6%	
- CORECTIM	4,377	+806	+22.6%	
- ANTEBATE	2,578	+491	+23.5%	
- LOCOID	921	+170	+22.8%	
- Other	347	-120	-25.7%	

#### **CORECTIM**

 Growth in revenue due to an increase in the number of patients prescribed the drug, including pediatric patients, and an increase in the amount used per patient

#### **ANTEBATE**

 Revenue increased due to higher sales volume resulting mainly from a switch from generic products

#### **LOCOID**

Revenue increased due to the positive impact of NHI drug price revisions and increased sales volume

# **Net Sales - Allergens and Other Areas**

Allergens			
	vs. Q2 2		2023
(Millions of yen)	Q2 2024	Increase/decrease	Pct. change
Net sales - Allergens	11,019	+1,009	+10.1%
- CEDARCURE	5,753	+529	+10.1%
- MITICURE	5,186	+500	+10.7%
- Other	79	-20	-20.6%

#### **CEDARCURE**

• Although limited shipments continue, sales volume increased due to the acquisition of a number of new patients, resulting in increased revenue

#### **MITICURE**

 Sales volume increased as a result of growth in the number of new patients, resulting in increased revenue

Other			
	vs. Q2 2023		2023
(Millions of yen)	Q2 2024	Increase/decrease	Pct. change
Net sales - Other areas	3,475	+440	+14.5%
- BIO-THREE	2,231	+377	+20.4%
- ORLADEYO	830	+94	+12.8%
- Other	412	-31	-7.1%

#### **BIO-THREE**

Revenue increase driven by the positive impact of NHI drug price revisions, coupled with probiotics market expansion

#### **ORLADEYO**

 Currently in a growth phase, sales volume has risen due to an increase in the number of new patients, resulting in increased revenue

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# **Assumptions for Revised Forecasts**

#### **Progress up to the second quarter**

# O1 Strong topline growth that exceeds plan

## 102 Increase in cost of sales

# R&D expenses are in line with previous forecasts

# SG&A expenses (excluding R&D expenses) are in line with previous forecasts

#### **Assumptions for revised forecasts**

#### Revised upward assuming current solid momentum continues

- - Upwardly revised growth in the areas of renal disease and hemodialysis, skin disease, and allergens
  - Product launch of tapinarof (development number: JTE-061, product name: VTAMA® Cream; hereafter "VTAMA®") was already factored into the previous forecast. No major changes

# Tough business environment continues; costs exceeding previous forecasts are factored in

- Factored in the impact of sales volume increase
- Change in exchange rate assumption (previous forecast: EUR=160JPY/revised forecast EUR=175JPY)

# No major changes in development schedule; refined expense forecasts

- R&D is generally progressing according to schedule. Refined expense forecasts

#### With sales-related expenses factored in, same level as forecasted

- Revised sales-related expenses
  - Due to efficient implementation of various measures, overall SG&A expenses (excluding R&D expenses) remain at the same level as previously forecast

# **Revised Forecasts for 2024 Performance**

Net sales and each income indicator are revised upward

	Revised	Revised vs. Previous forecast		vs. PY
(Millions of yen)	forecast	Increase /decrease	Pct. change	Pct. change
Net sales	60,700	+2,100	+3.6%	+11.1%
Gross profit	26,800	+300	+1.1%	+8.1%
Operating income	6,300	+500	+8.6%	+25.1%
Operating income before R&D expenses*	9,500	+250	+2.7%	+11.4%
Net income	4,800	+100	+2.1%	+16.5%
(Reference) R&D expenses	3,200	-250	-7.2%	-8.3%

<sup>\*</sup> We are actively investing in R&D for the time being, in order to obtain in-licensed drugs in the future. For this reason, we have set operating income before R&D expenses as a numerical income indicator for the Medium-Term Management Plan.

#### **Net sales**

Revised upward in anticipation of higher growth than previously forecast in the areas of allergens, renal disease and hemodialysis, and skin disease

#### **Operating income**

- The positive impact of the following factors resulted in upward revision
  - (+) Upward revision of net sales, decrease in R&D expenses
  - (-) Higher cost of sales

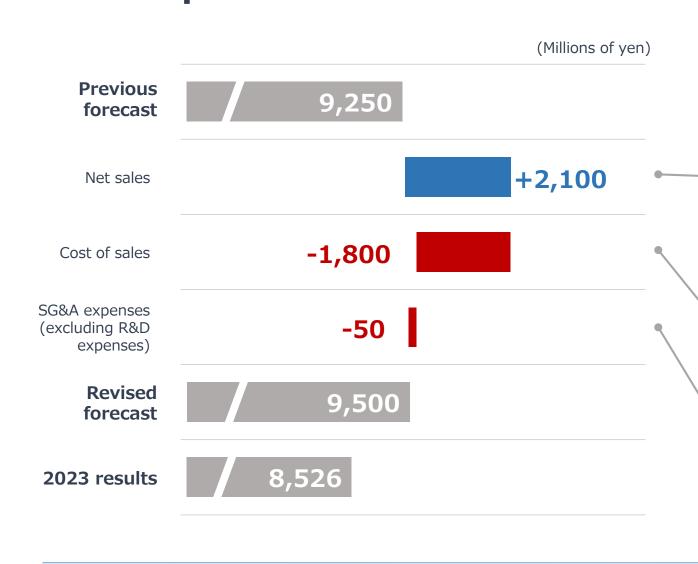
## Operating income before R&D expenses

Although cost of sales increased, forecast was revised upward to reflect the increase in net sales

#### **Net income**

Although income taxes and non-operating expenses increased, the increase in operating income resulted in upward revision

# Factors behind Change in Operating Income before R&D Expenses



#### Primary factors behind the change

- CEDARCURE: While there is no change to the limited shipments in 2024, sales volume has increased due to the acquisition of new patients exceeding assumptions for the previous forecast
- Riona: Growth due to increased net sales for iron deficiency anemia and a revision of assumptions regarding the timing of generic drug product launches
- Reflects the impact of NHI drug price revisions, etc.
- Increase in volume of sales
- Review of exchange rate assumptions given current trends
- Although sales-related expenses have increased in line with net sales growth, SG&A expenses remain at the level previously forecast due to efficient execution of expenses

# Net Sales - Renal Disease and Hemodialysis, Skin Disease

## Renal disease and hemodialysis

	Revised	vs. Previou	vs. Previous forecast	
(Millions of yen)	forecast	Increase/decrease	Pct. change	Pct. change
Net sales - Renal disease and hemodialysis	10,920	+900	+9.0%	-8.1%
- Riona	7,590	+890	+13.3%	+1.0%
- REMITCH	1,710	-120	-6.6%	-37.3%
- Other	1,620	+130	+8.7%	-1.7%

#### **Riona**

 Revised upward based on a review of assumptions related to the timing of generic drug product launches, in addition to first-half results

#### **REMITCH**

 Revised downward due to the impact of the system of selective treatment with long-listed drugs

#### Skin disease

	Revised	vs. Previous forecast		vs. PY
(Millions of yen)	forecast	Increase/decrease	Pct. change	Pct. change
Net sales – Skin disease	17,390	+330	+1.9%	+21.9%
- CORECTIM	8,680	-120	-1.4%	+16.5%
- ANTEBATE	4,980	+210	+4.4%	+9.9%
- LOCOID	1,950	+330	+20.4%	+36.6%
- Other	1,780	-90	-4.8%	+108.4%

#### **CORECTIM**

 While momentum remains strong, revised downward due to elaboration of the impact of VTAMA® product launch

#### **ANTEBATE**

Revised upward given the momentum in the first half of the year

#### **LOCOID**

Revised upward due to the positive impact of NHI drug price revisions

# **Net Sales - Allergens and Other Areas**

Allergens					
	Revised	vs. Previoเ	ıs forecast	vs. PY	
(Millions of yen)	forecast	Increase/decrease	Pct. change	Pct. change	
Net sales - Allergens	24,800	+1,010	+4.2%	+14.4%	
- CEDARCURE	13,110	+500	+4.0%	+15.4%	
- MITICURE	11,530	+510	+4.6%	+13.6%	
- Other	160		_	-11.1%	

#### **CEDARCURE**

- Revised upward due to the acquisition of new patients exceeding assumptions for the previous forecast
- No change in the outlook for continued limited shipments in 2024

#### **MITICURE**

Revised upward based on first-half results

Other				
	Revised	vs. Previou	ıs forecast	vs. PY
(Millions of yen)	forecast	Increase/decrease	Pct. change	Pct. change
Net sales - Other area	7,320	-130	-1.7%	+12.6%
- BIO-THREE	4,600	+200	+4.5%	+13.8%
- ORLADEYO	1,950	-320	-14.1%	+26.1%
- Other	770	-10	-1.3%	-15.4%

#### **BIO-THREE**

Revised upward based on first-half results

#### **ORLADEYO**

 While currently in a growth phase, showing growth compared to the previous fiscal year, revised downward due to a larger-thanexpected impact of competing products, etc.

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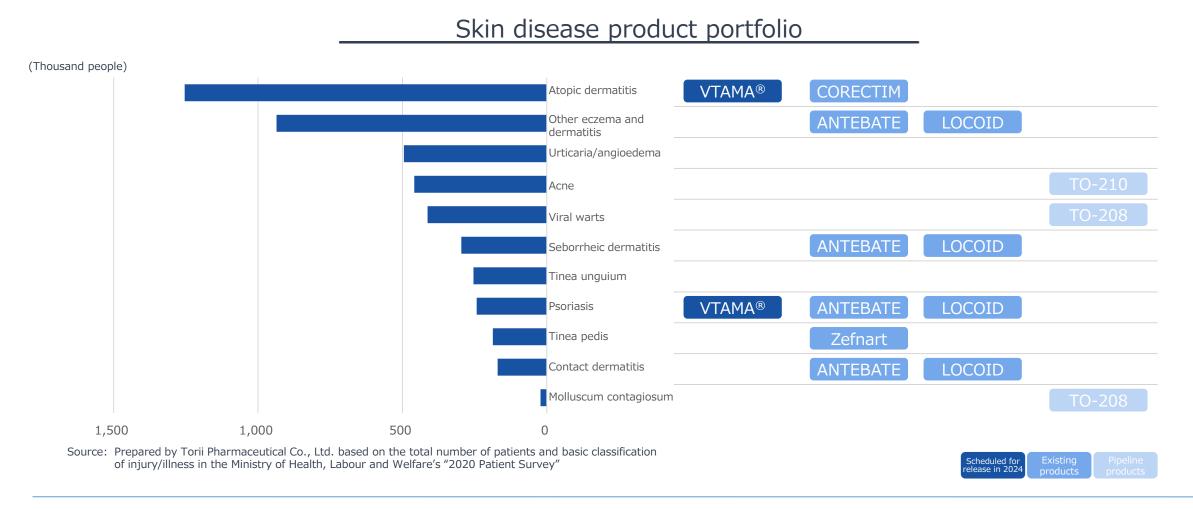
# VTAMA® Cream: Marketing Approval Obtained

■ In June 2024, JT obtained marketing approval for VTAMA® Cream 1% in Japan, indicated for the treatment of atopic dermatitis and plaque psoriasis

	VTAMA® Cream	(Reference) CORECTIM
Indications	Atopic dermatitis, plaque psoriasis	Atopic dermatitis
Action mechanism	Drug containing novel compounds targeting the aryl hydrocarbon receptor (AhR)	JAK inhibitor
Dosage form	Cream	Ointment
Use	Once daily	Twice daily

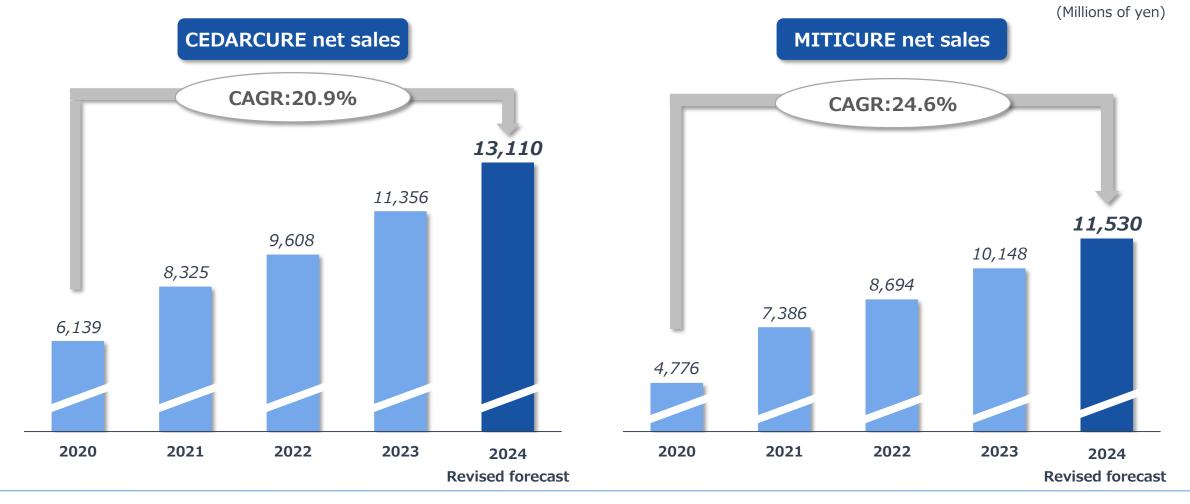
# VTAMA® Cream: Strengthening Skin Disease Product Portfolio

Strengthening our product portfolio for skin diseases through VTAMA® Cream



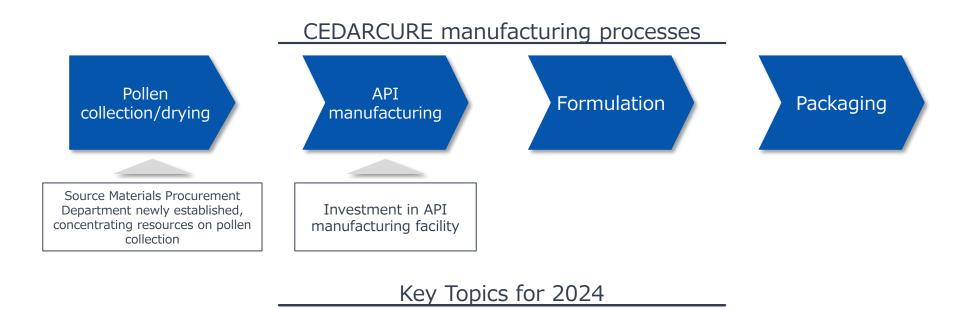
# Allergens: Growth of CEDARCURE and MITICURE

- The allergens area has been a driver of growth, continuing to show strong growth over the past few years
- We will continue to actively promote the spread of allergen immunotherapy and increased production of CEDARCURE



# Allergens: Initiatives to Increase Production of CEDARCURE

- To increase production, we are investing resources in pollen collection and active pharmaceutical ingredient (API) manufacturing processes. New API manufacturing facility scheduled to begin operation in 2025
- Limited shipments expected in 2024, as originally planned



✓ Pollen collection : Securing the planned amount

✓ New API manufacturing facility : Construction progressing smoothly. Start of operations scheduled for 2025 as originally planned

✓ Future supply and demand outlook: Continue to monitor and examine closely. Plan to offer outlook for 2025 timed with release of full-year results

# Factors behind Increase in Cost of Sales and Future Outlook



■ Cost of sales for the second quarter of 2024 increased by approx. 1.9 billion yen year-on-year. Factors behind the increase are as follows:

- Impact of volume increase : Approx. 1.3 billion yen [approx. 65%]

- Impact of increase in purchase prices (including exchange rate effects) : Approx. 0.6 billion yen [approx. 30%]

Other : Approx. 0.1 billion yen [approx. 5%]

## **Future outlook for cost of sales**

- Tough business environment expected to continue for the time being
- Taking into account the current exchange rate trend, the exchange rate assumption for the remaining period has been revised to EUR=175 yen (the previous forecast was EUR=160 yen)

#### **Future actions**

- We will continue to work with business partners to create a cost structure that is in line with the business environment
- We aim to improve our operating income margins (before R&D expenses) by implementing efficient measures and execution of expenses across all costs, not just cost of sales

# **Status of Intensive Business Investment from 2023-2027**

■ The specific amount of investment planned as of the end of June 2024 is approx. 16 billion yen (approx. 5.5 billion yen of this has been paid/confirmed)

drug (GRAZAX) for treatment of grass pollen allergy

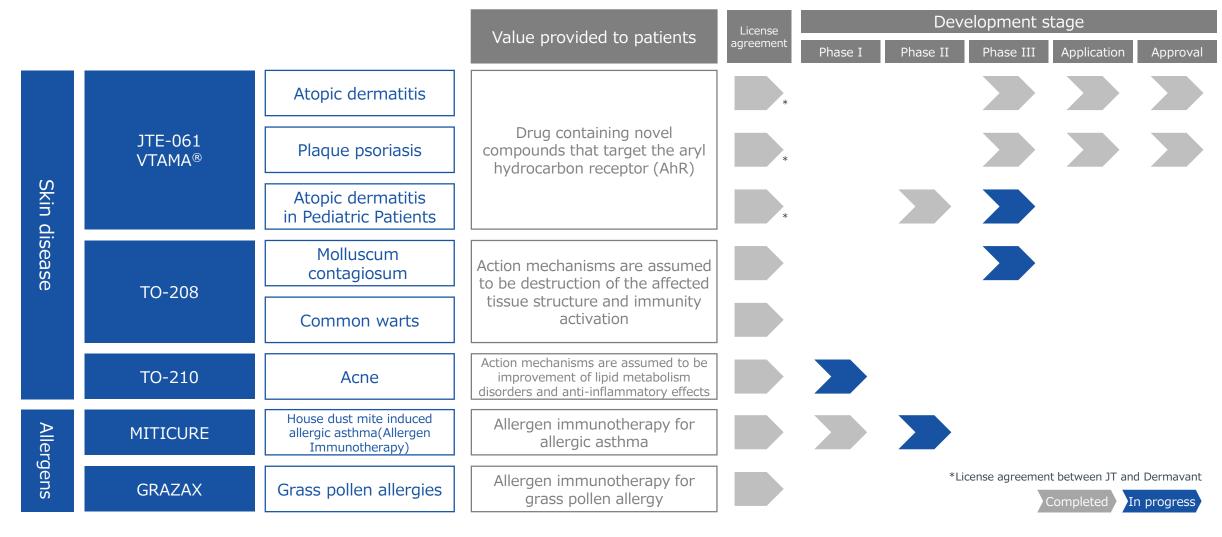
■ We will continue to make aggressive business investments in order to achieve sustainable growth over the medium to long term

Major investments Amount Progress **Acquisition of new in-licensed products** Approx. 1.6 Lump sum payment upon conclusion of the license agreement for acne treatment (TO-210) Paid billion yen Maximizing the value of existing and pipeline products Capital investment in API manufacturing to accommodate increased sales volume of Approx. 3.0 Decisions made/partially paid **CEDARCURE** billion yen Milestone payments based on progress in the development of a skin disease treatment for molluscum contagiosum and common warts (TO-208) Payments to be made based on Total: Approx. Milestone payments based on progress in the development of an acne treatment (TO-210) development progress 10 billion yen Milestone payments based on progress in the development of an allergen immunotherapy

Only major investments decided upon by June 2024 are listed. The timing of payments will vary on a case-by-case basis. Please note that milestone payments may not be made, depending on the development status. In addition, the amount paid in Japanese yen may vary depending on the exchange rate at the time of payment.

# **Development Pipeline**

■ TO-210: Phase I started (April); VTAMA®: approved for atopic dermatitis and plaque psoriasis (June)



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# **Status of Corporate Governance**

- In March of this year, we transitioned to a new organizational design and membership for the Board of Directors. We will continue to strengthen corporate governance
  - Transition to a company with an audit and supervisory committee
  - ✓ All three members of the Audit and Supervisory Committee will be independent outside directors, further strengthening the audit and supervisory function over the Board of Directors
  - ✓ A voluntary Nomination and Compensation Advisory Committee consisting of three independent outside directors has been established. The goal is to enhance deliberations regarding the nomination and compensation of directors and executive officers, further enhancing procedural transparency, objectivity, and fairness

#### **New outside directors**

- ✓ Three new outside directors, Takaharu Matsumura, Mihoko Manabe, and Kenichi Fujita, were appointed
- ✓ Realizing a well-balanced Board of Directors, with diverse backgrounds, expertise, and experience

#### Two-representative-director system

- ✓ Nobumasa Kondo was appointed as new Executive Deputy President
- ✓ The new system will enable us to address management issues more appropriately and quickly than before, and also strengthen our ability to make decisions and execute business operations from a companywide perspective

## Members of the Board of Directors



Representative Director,
President and CEO

Goichi Matsuda



Representative Director, Executive Deputy President Nobumasa Kondo



Outside Director and Audit and Supervisory Committee Member Takaharu Matsumura



Outside Director and Audit and Supervisory Committee Member Mihoko Manabe



Outside Director and Audit and Supervisory Committee Member Kenichi Fuilta

#### **Integrated Report 2023 published**

✓ Starting this year, we will discontinue the annual report and issue the Integrated Report 2023

https://www.torii.co.jp/ir/library/annual/



<sup>\*</sup>This report is currently available only in Japanese. The English version is scheduled for release in September.

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# **Closing Remarks**

# Financial Results for Q2 2024

✓ Even in a tough business environment, we have realized strong growth in net sales and operating income before R&D expenses

## **Revised Financial Forecasts for 2024**

✓ Net sales and income indicators have all been revised upwards

## **Business Update**

✓ Marketing approval for VTAMA® Cream 1% obtained, further strengthening our product portfolio for skin diseases

#### **Shareholder returns**

✓ No change to planned annual dividend of 120 yen per share

# **Important Notice**

The performance forecasts and other forward-looking statements in this document are based on information available as of the date of publication of this document. They contain risks and uncertainties. The Company offers no guarantee that it will achieve these forecasts.

Please be aware that actual business results may vary significantly from these forecasts based on a number of factors. Further, regardless of new information, future events or other results, the Company may not revise or update its forecasts.

While information about pharmaceuticals (including those in development) is included here, it is not intended as an advertisement or medical advice.



# Torii Pharmaceutical's Purpose

We are committed to sincerely serving patients, their families, and those involved in medical care. We contribute to the healthy recovery of patients, as well as to a happy, enriched life free from fear of illness.

We will flexibly change and adapt to meet the needs of the times and the environment, while retaining the trust we have earned over our long history, and we will continue to take on the challenge of contributing to healthcare that only we can make.