

## 【Event Summary】

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Date : August 2, 2024

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(Presentation: 30 minutes, Q&A: 30 minutes)

Venue : Webcast

Number of Speakers : 2

Goichi Matsuda Representative Director,  
President and Chief Executive Officer

Nobumasa Kondo Representative Director,  
Executive Deputy President

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

August 2, 2024  
Torii Pharmaceutical Co., Ltd.



I am Goichi Matsuda, President and CEO of Torii Pharmaceuticals.

Thank you for joining me for today's financial results briefing despite your busy schedules.

Today I will explain our financial results for the second quarter of 2024 and the revised forecasts for 2024. These were announced on July 31<sup>st</sup>.

## **AGENDA**

- **Financial Results for Q2 2024**
- **Revised Financial Forecasts for 2024**
- **Business Update**
- **Status of Corporate Governance**
- **Closing Remarks**

Here is today's agenda.

## AGENDA

- **Financial Results for Q2 2024**
- Revised Financial Forecasts for 2024
- Business Update
- Status of Corporate Governance
- Closing Remarks

First, I would like to explain our results for the second quarter of 2024. Please take a look at slide 4.

# 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

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

\* 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

Although the business environment remained challenging during the second quarter, we achieved double-digit growth in both sales and operating income before R&D expenses.

Sales increased by 10.2% year on year due to ongoing strong growth in the areas of skin disease and allergens. While gross profit increased by 5.7% compared to the previous year, it did not grow as much as sales due to the increased cost of sales.

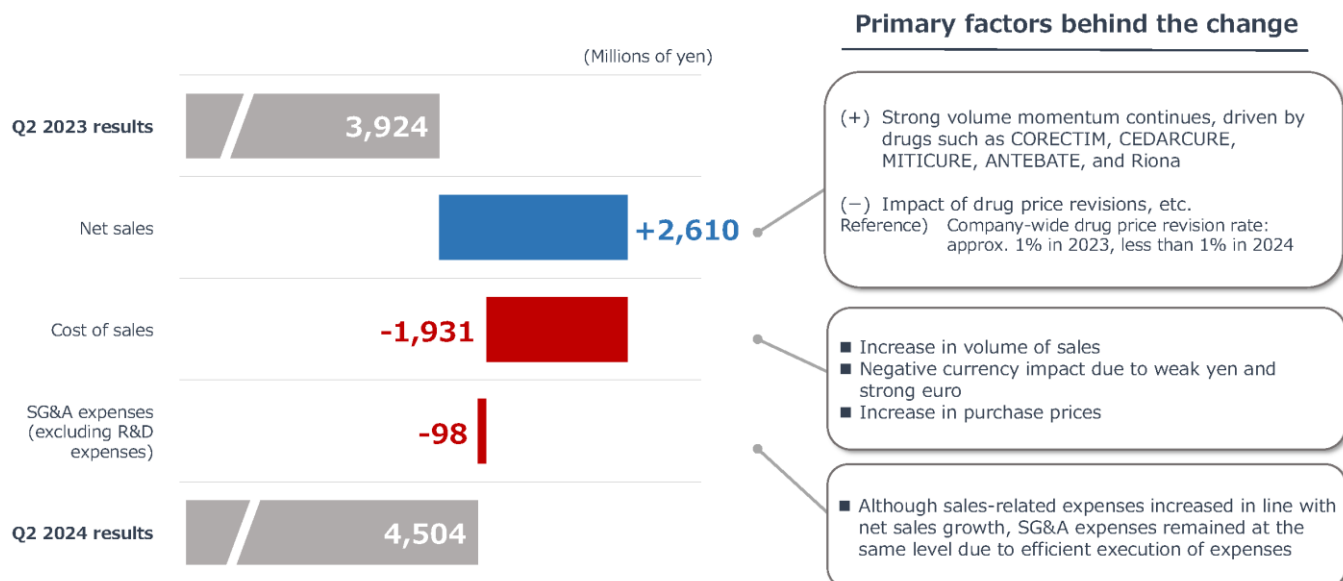
Due to the increase in sales and a decrease in R&D expenses, operating income increased by 107.9% over last year, despite the increase in the cost of sales.

Although R&D expenses decreased significantly with the absence of the contracted one-time payment for in-licensed products of approximately ¥1.6 billion that was recorded in the previous year, R&D is largely progressing as planned.

Despite the increase in sales costs, operating income before R&D expenses increased by 14.8% over last year due to sales growth.

Finally, although income taxes and non-operating expenses increased, the increase in operating income led to a 104.4% increase in net income compared to the same period last year.

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



Next, I will explain the factors involved in the change in operating income before R&D expenses.

Please take a look at slide 5.

Sales increased by approximately ¥2.6 billion.

This is because the strong volume growth for individual products such as CORECTIM, CEDARCURE, MITICURE, ANTEBATE, and Riona outweighed the negative impact of drug price revisions.

At the same time, the cost of sales increased from last year, negatively impacting operating income by roughly ¥1.9 billion. Reasons for this include an increase in sales volume, an increase in purchase prices, as well as the negative impact of fluctuations in currency exchange rates due to the weak yen against the euro.

I will explain cost of sales in more detail later.

Selling, general and administrative expenses, excluding R&D expenses, have remained at the same level as the previous year due to efficient expense execution even though there was an increase in sales-related expenses.

As a result, operating income before R&D expenses increased by approximately ¥580 million compared to the same period last year.

# Net Sales - Renal Disease and Hemodialysis, Skin Disease

## Renal disease and hemodialysis

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

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

Next, I will explain sales figures for each area.

Please look at slide 6.

First, I will talk about the renal disease and hemodialysis area.

Although Riona was negatively impacted by NHI drug price revisions, sales increased by 8.5% over last year due to an increase in sales volume. This increase was the result of growth in prescriptions for iron deficiency anemia.

REMITCH sales decreased by 35.4% year on year due to the negative impact of drug price revisions as well as lower sales volume due to the appearance of generic drugs.

Because of this, sales in the renal disease and hemodialysis area decreased by 3.2% year on year.

Next, I would like to talk about the skin disease area.

CORECTIM continued to show strong growth, with an increase in sales of 22.6% compared to last year.

With the disappearing gap between generic and brand drug prices, sales of ANTEBATE increased by 23.5% over last year as more patients switch to using ANTEBATE.

Sales for LOCOID increased by 22.8% compared to the same period last year due to the positive impact of the 2024 drug price revisions and an increase in sales volume.

As a result, the skin disease area saw a sales increase of 19.6% compared to last year.

# Net Sales - Allergens and Other Areas

## Allergens

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

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

Next, I will talk about the allergens area and other areas.

Please look at slide 7.

First, I will explain the allergens area.

As previously noted, the limited shipments of CEDARCURE continue, so there is no change in our outlook for these limited shipments in 2024.

Despite these circumstances, with the acquisition of new patients, sales volume increased. This resulted in a 10.1% increase in sales compared to the same period last year.

Due to the continued increase in new patients seeking allergen immunotherapy, sales for MITICURE increased by 10.7% over the previous year.

Due to these factors, overall sales in the allergens area increased by 10.1% compared to the same period last year.

In other areas, sales of BIO-THREE and ORLADEYO continued to grow, resulting in a 14.5% increase in sales compared to the same period last year.



## AGENDA

- Financial Results for Q2 2024
- **Revised Financial Forecasts for 2024**
- Business Update
- Status of Corporate Governance
- Closing Remarks

Next, I will talk about our revised forecasts for 2024.

Please look at slide 9.

# Assumptions for Revised Forecasts

## Progress up to the second quarter

**01** Strong topline growth that exceeds plan

**02** Increase in cost of sales

**03** R&D expenses are in line with previous forecasts

**04** 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

First, I would like to explain the assumptions behind this revised forecasts.

Please look at slide 9.

As I noted in the results section, sales showed strong momentum and grew beyond our previous forecast.

As a result, we have revised our sales forecast upward based on the assumption that the current strong momentum will continue.

Manufacturing and marketing approval for VTAMA® was acquired on June 24. This has already been factored into our previous sales forecast, and there is no significant change in this revised forecast.

The increase in cost of sales is currently higher than the increase in sales compared to the previous year.

We think this challenging environment will continue for a while, so in this revised forecast we have decided to incorporate a higher cost of sales than the previous forecast.

R&D and selling, general and administrative expenses are generally in line with previous forecasts, and there are no major changes in our outlook.

# Revised Forecasts for 2024 Performance

- Net sales and each income indicator are revised upward

(Millions of yen)	Revised forecast	vs. Previous forecast		vs. PY	
		Increase /decrease	Pct. change	Pct. change	
Net sales	<b>60,700</b>	+2,100	+3.6%	+11.1%	<b>Net sales</b> <ul style="list-style-type: none"> <li>Revised upward in anticipation of higher growth than previously forecast in the areas of allergens, renal disease and hemodialysis, and skin disease</li> </ul>
Gross profit	<b>26,800</b>	+300	+1.1%	+8.1%	<b>Operating income</b> <ul style="list-style-type: none"> <li>The positive impact of the following factors resulted in upward revision (+) Upward revision of net sales, decrease in R&amp;D expenses (-) Higher cost of sales</li> </ul>
Operating income	<b>6,300</b>	+500	+8.6%	+25.1%	<b>Operating income before R&amp;D expenses</b> <ul style="list-style-type: none"> <li>Although cost of sales increased, forecast was revised upward to reflect the increase in net sales</li> </ul>
Operating income before R&D expenses*	<b>9,500</b>	+250	+2.7%	+11.4%	
Net income	<b>4,800</b>	+100	+2.1%	+16.5%	<b>Net income</b> <ul style="list-style-type: none"> <li>Although income taxes and non-operating expenses increased, the increase in operating income resulted in upward revision</li> </ul>
(Reference) R&D expenses	<b>3,200</b>	-250	-7.2%	-8.3%	

\* 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.

Next, I will explain our revised earnings forecasts for 2024.

Please look at slide 10.

Based on current performance, the sales forecast has been revised upward by 3.6%.

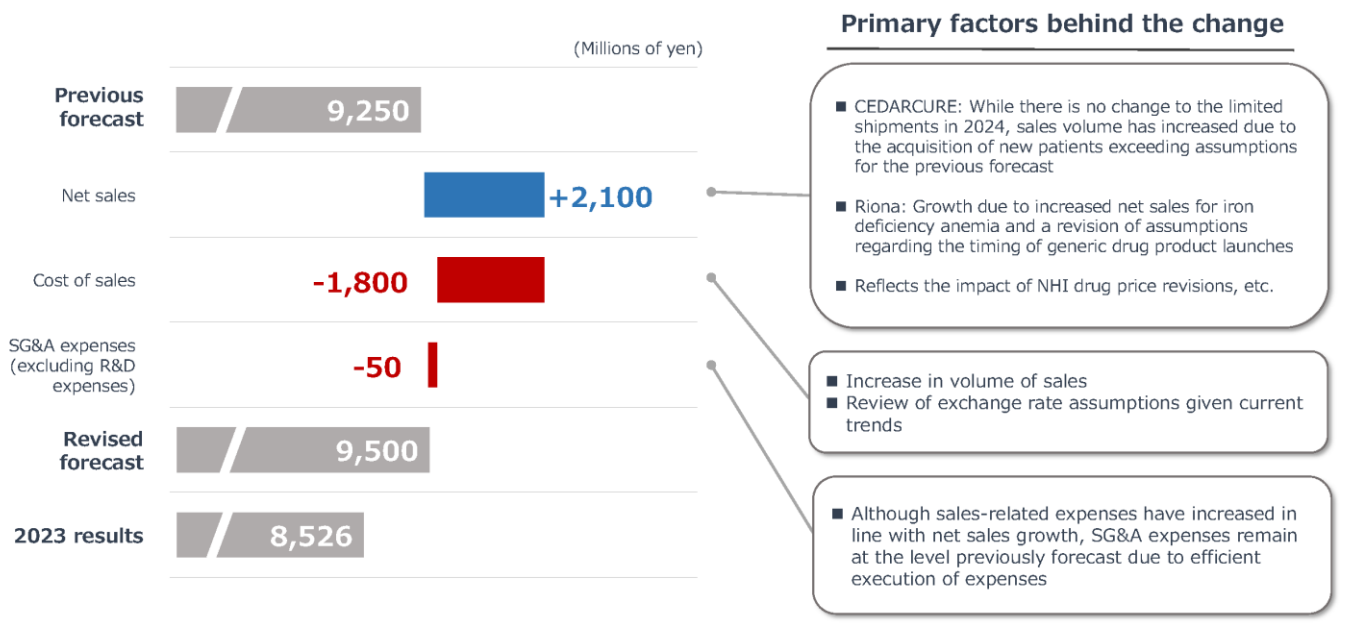
Although the operating income forecast incorporated a higher cost of sales, it has been revised upward by 8.6% due to an increase in sales and a decrease in R&D expenses.

R&D expenses are 7.2% less than the previous forecast because we have refined our estimates for future expenses.

As I explained in the previous slide, this is due to our refined expense forecasts, and R&D itself is progressing largely according to plan.

Due to an increase in operating income, net income has been revised upward by 2.1%. This is despite increases in income taxes and non-operating expenses.

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



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Next, I will explain the factors behind the change in operating income before R&D expenses.

Please look at slide 11.

Sales have been revised upward by ¥2.1 billion.

This is the result of strong volume momentum for CEDARCURE and Riona as well as the impact of the April 2024 drug price revisions.

As I mentioned previously, the cost of sales is expected to increase by ¥1.8 billion from the previous forecast as the impact of increased sales volume as well as revised assumptions about the exchange rate.

Although there is an increase in sales-related expenses, as we continue to execute expenses efficiently overall, we expect selling, general and administrative expenses, excluding R&D expenses, to remain at about the same level as previously forecasted.

Therefore, operating income before R&D expenses is expected to be ¥9.5 billion, which is an upward revision of ¥250 million compared to the previous forecast.

# Net Sales - Renal Disease and Hemodialysis, Skin Disease

## Renal disease and hemodialysis

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

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

Next, I will talk about sale figures for each of the business areas.

Please look at slide 12.

First, I will explain the renal disease and hemodialysis area.

We revised our Riona forecast upward by 13.3% based on the results in the first half of the year as well as on a review of assumptions, such as delays in the timing of the launch of generic versions from the first half to the second half of the year.

In this revision, REMITCH has been revised downward by 6.6%, taking into consideration the impact of the selective treatment system for long-listed products.

As a result of these factors, sales for the renal disease and hemodialysis area have been revised upward by 9.0%.

Next, I will talk about the skin disease area.

CORECTIM has been showing strong growth, and we believe this momentum will continue.

However, as a result of the impact the launch of VTAMA® will have on CORECTIM in the second half of the year, we have made a slight downward revision of 1.4%.

Based on its currently solid performance, ANTEBATE has been revised upward by 4.4%.

Given the current increase in sales volume as well as the positive impact the April 2024 drug price revisions had on unit prices, we have revised our forecast for LOCOID upward by 20.4%.

Due to these factors, sales in the skin disease area have been revised upward by 1.9%.

# Net Sales - Allergens and Other Areas

## Allergens

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

(Millions of yen)	Revised forecast	vs. Previous forecast		vs. PY
		Increase/decrease	Pct. change	Pct. change
Net sales - Other area	<b>7,320</b>	-130	-1.7%	+12.6%
- BIO-THREE	<b>4,600</b>	+200	+4.5%	+13.8%
- ORLADEYO	<b>1,950</b>	-320	-14.1%	+26.1%
- Other	<b>770</b>	-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-than-expected impact of competing products, etc.

Next, I will discuss the allergens area and other areas.

Please look at slide 13.

First, I will talk about the allergens area.

As I mentioned previously, there is no change to our outlook for CEDARCURE, which will continue to have limited shipments through 2024.

However, even with the limited shipments, the number of new patients has surpassed previous assumptions, so we have revised our forecast upward by 4.0%.

We have revised our forecast for MITICURE upward by 4.6% due to its strong performance in the first half of the year.

As a result, sales in the allergens area have been revised upward by 4.2%.

In other areas, BIO-THREE has been revised upward, but ORLADEYO has been revised downward. As a result, there is an overall downward revision of 1.7%.

## AGENDA

- Financial Results for Q2 2024
- Revised Financial Forecasts for 2024
- **Business Update**
- Status of Corporate Governance
- Closing Remarks

On the next slide, I will mainly discuss topics which had updates in the first half of 2024.  
Please look at slide 15.

## VTAMA<sup>®</sup> Cream: Marketing Approval Obtained

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

	VTAMA <sup>®</sup> 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

In June, we acquired manufacturing and marketing approval in Japan for VTAMA<sup>®</sup> Cream 1%, development number “JTE-061.” This drug is indicated for treatment of atopic dermatitis and plaque psoriasis.

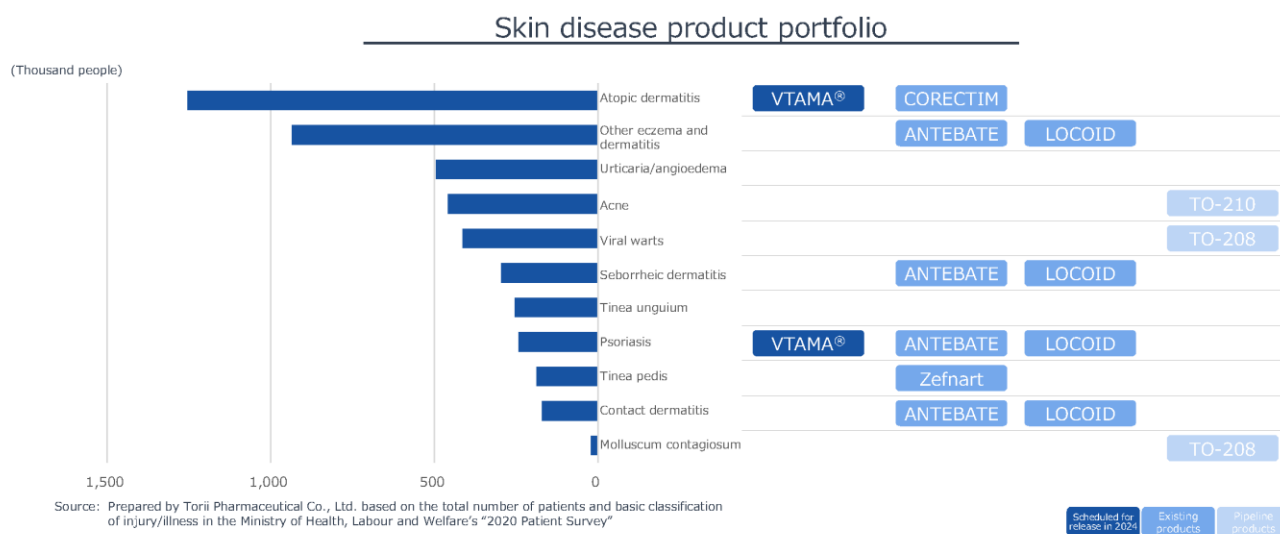
VTAMA<sup>®</sup> suppresses the production of inflammatory cytokines by activating AhR, a cytosolic ligand-dependent transcription factor. It is also a non-steroid, small molecule therapeutic AhR modulating agent that induces gene expression of skin barrier function-related molecules and anti-oxidant molecules.

We hope that VTAMA<sup>®</sup> will become a new option for the treatment of atopic dermatitis and plaque psoriasis.



# VTAMA® Cream: Strengthening Skin Disease Product Portfolio

■ Strengthening our product portfolio for skin diseases through VTAMA® Cream



Please look next at slide 16.

We have always had a comprehensive portfolio of products that cover a wide range of conditions in the skin disease area. These include CORECTIM, ANTEBATE, and LOCOID.

With the addition of VTAMA®, our product portfolio in the area of skin diseases will be even stronger.

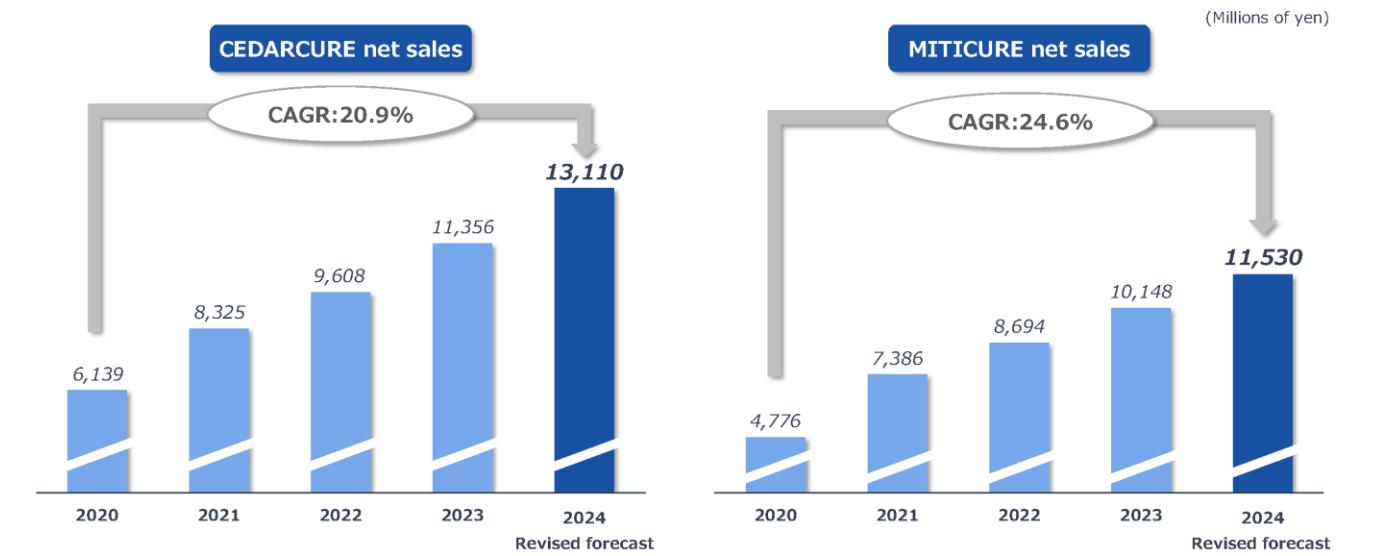
We anticipate that VTAMA® will lead further growth in the skin disease area, one of our main growth drivers.

Besides VTAMA®, we are also developing “TO-208,” which is indicated for the treatment of molluscum contagiosum and common warts, and “TO-210,” which is indicated for the treatment of acne.

With these products, we will provide value to many patients and continue to increase our support in the area of skin diseases.

# 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



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With the next slide, I will talk about the allergens area.

Please look at slide 17.

We have the allergens area positioned as one of our growth drivers, and it has continued to grow strongly over the past several years.

As this slide shows, the average annual growth rate for CEDARCURE and MITICURE has exceeded 20% over the period since 2020.

We believe this strong growth is primarily the result of the continued spread of allergen immunotherapy.

With CEDARCURE, on the other hand, we continue to receive orders for increased dosage formulations that far exceed what we anticipated, so we are taking measures to limit shipments of increased dosage formulations.

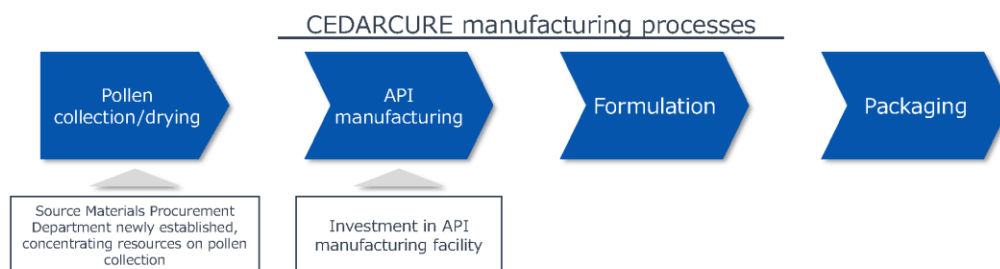
There are two types of CEDARCURE: an increased dosage formulation and a maintenance formulation. In order to ensure that we have a stable supply for new patients or for those who are already taking the drug, we have implemented limited shipping.

Because the maintenance formulation is not subject to the same shipping limits, there is no problem ensuring stable supply for patients already taking it as well as a certain number of new patients.

In the next slide, I will talk about our efforts to increase the 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



## Key Topics for 2024

- ✓ 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

Please look at slide 18.

The manufacturing process for CEDARCURE is broadly divided into four stages: pollen collection and drying, active pharmaceutical ingredient (API) manufacturing, formulation, and packaging.

Of these, we are investing resources in pollen collection and drying and API manufacturing in an effort to increase production of CEDARCURE.

As for pollen collection and drying, the Source Materials Procurement Department is taking the lead in implementing various initiatives aimed at increasing the amount of cedar pollen collected.

Pollen collection occurs in winter and spring. This year, we were able to collect the anticipated amount of pollen, so we feel that we will be able to increase the production of CEDARCURE in the future.

With regard to API manufacturing, as previously conveyed, we have decided to make capital investments of approximately ¥3 billion to expand our API manufacturing facility.

Construction is progressing smoothly and the manufacturing facility is scheduled to begin operation as planned in 2025.

Finally, we will continue to monitor CEDARCURE's future supply and demand.

We plan to provide information about our outlook for 2025 onward in our full financial report for the year.

# Factors behind Increase in Cost of Sales and Future Outlook

## Factors behind increase in cost of sales

- 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

Next, I will explain the factors influencing the increase in sales cost as well as our future outlook.

Please look at slide 19.

As I have said, sales costs are on an upward trend and have increased by approximately ¥1.9 billion in the second quarter of 2024 compared to the same quarter last year.

This rise is due to the impact of a sales volume increase amounting to roughly ¥1.3 billion, the impact of an increase in purchase prices, including exchange rate effects, which amounts to around ¥600 million, and other factors accounting for approximately ¥100 million.

We expect this challenging business environment to continue for some time, and we don't have an optimistic outlook. Going forward, we will continue to work with our business partners to find an appropriate cost structure in which the cost of sales reflects the business environment.

Further, we are working to improve our operating income margin before R&D expenses. We will do this by implementing efficient policy initiatives and expense execution across not just the cost of sales but SG&A and all other expenses.

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

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

\* 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.

Next, I will explain our investment situation during the period of concentrated investment between 2023 and 2027. Please look at slide 20.

To ensure sustainable growth in 2030 and beyond, the five-year period between 2023 and 2027 will be one of concentrated investments of approximately ¥40 billion.

As of the end of June 2024, the actual amount of planned investment is approximately ¥16 billion, with about ¥5.5 billion already spent or earmarked.

Major investments are:

one-time contracted payment of approximately ¥1.6 billion for the license agreement for the acne drug TO-210; capital investment of approximately ¥3.0 billion for API manufacturing in order to accommodate increased sales volume of CEDARCURE.

milestone payments of approximately ¥10 billion in total for three products in the development pipeline: TO-208, TO-210, and GRAZAX.

The milestone payments will be made based on development progress, and payments may be withheld depending on development status.

We will continue to make proactive business investments to realize sustainable growth in the medium to long term.

# Development Pipeline

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

			Value provided to patients	License agreement	Development stage				
					Phase I	Phase II	Phase III	Application	Approval
Skin disease	JTE-061 VTAMA®	Atopic dermatitis	Drug containing novel compounds that target the aryl hydrocarbon receptor (AhR)	▶*			▶	▶	▶
		Plaque psoriasis		▶*			▶	▶	▶
		Atopic dermatitis in Pediatric Patients		▶*	▶	▶			
	TO-208	Molluscum contagiosum	Action mechanisms are assumed to be destruction of the affected tissue structure and immunity activation	▶			▶		
		Common warts		▶			▶		
TO-210	Acne	Action mechanisms are assumed to be improvement of lipid metabolism disorders and anti-inflammatory effects	▶	▶					
Allergens	MITICURE	House dust mite induced allergic asthma (Allergen Immunotherapy)	Allergen immunotherapy for allergic asthma	▶	▶	▶			
	GRAZAX	Grass pollen allergies	Allergen immunotherapy for grass pollen allergy	▶					

\*License agreement between JT and Dermavant  
Completed In progress

Now I will talk about the development pipeline.

Please look at slide 21.

As a first-half update, in April, we started Phase I of a clinical trial in Japan for TO-210 for the treatment of acne. Further, as I already mentioned, JTE-061, VTAMA®, has already received manufacturing and marketing approval in Japan for the treatment of atopic dermatitis and plaque psoriasis.

JTE-061 is currently in Phase III clinical trial for use with pediatric patients with atopic dermatitis in Japan.

## AGENDA

- Financial Results for Q2 2024
- Revised Financial Forecasts for 2024
- Business Update
- **Status of Corporate Governance**
- Closing Remarks

Next, I will discuss corporate governance.

Please look at slide 23.

# 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 company-wide perspective

## Members of the Board of Directors



## 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/>



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

In March, we transitioned to a new organizational design and new members of the Board of Directors. We have transitioned to being a company with an audit and supervisory committee, and Mr. Matsumura, Ms. Manabe, and Mr. Fujita have been newly appointed as outside directors. Mr. Kondo has been appointed as the new Executive Deputy President and Representative Director.

We have already had a variety of discussions with the new Board of Directors, and I feel we have been able to have lively and substantive discussions.

We will use this new organizational design and the new members of the Board to further develop and strengthen our corporate governance structure as we work to achieve sustainable growth and improve corporate value over the medium and long term.

Further, starting this year, we discontinued the Annual Report and at the end of June 2024, we issued the Integrated Report 2023.



## AGENDA

- Financial Results for Q2 2024
- Revised Financial Forecasts for 2024
- Business Update
- Status of Corporate Governance
- **Closing Remarks**

Finally, please take a look at slide 25.

## 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

Here is a brief summary of what I have shared at this briefing.

Despite the challenging business environment, we achieved strong growth in sales and operating income before R&D expenses in the second quarter of 2024.

Given these results, we have revised our financial forecasts for 2024, revising sales and all profit indicators upward. Additionally, with the manufacturing and marketing approval for VTAMA® received in June 2024, we have further strengthened our product portfolio in the skin disease area.

Finally, regarding shareholder returns, although we have revised our earnings forecasts for 2024, the annual dividend per share remains unchanged at ¥120.

This concludes my remarks.

Thank you.

## 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.

# Minutes of Q&A Session at the Financial Results Briefing for the First Six Month of the Fiscal Year Ending December 31, 2024

**Date and Time: Friday, August 2, 2024, 11:00-12:00**

**Attendees:**

**Goichi Matsuda, Representative Director, President and Chief Executive Officer**

**Nobumasa Kondo, Representative Director, Executive Deputy President**

## **Question 1**

The revised forecast states that CORECTIM has been revised downward due to refining the impact of VTAMA®. Taking the products of other companies into consideration, what position in the area of atopic dermatitis and psoriasis are CORECTIM and VTAMA® aiming for?

How do you think the safety of VTAMA®, given side effects such as acne, folliculitis, and headaches, will be evaluated by medical professionals?

## **Answer 1 (Kondo)**

Since comparative testing with CORECTIM or other drugs has not been carried out in clinical trials on VTAMA®, we cannot comment on such comparisons. We cannot say which patients will benefit from VTAMA®, but since symptoms differ from one patient to the next, we believe that adding VTAMA® as a treatment option will be of great benefit to patients with atopic dermatitis or psoriasis.

Further, since its launch, VTAMA® has had two indications, and one of its assets is that it can be proposed as part of a comprehensive package together with our other products in the area of skin disease. We are pursuing information sharing activities that leverage this fact.

As for safety, after the product is launched, we will provide pertinent information to doctors so they can prescribe it appropriately based on the patient and their condition.

## **Question 2**

Based on current exchange rate trends, what do you think about the exchange rate assumptions you have set?

## **Answer 2 (Kondo)**

CEDARCURE and MITICURE are imported from Europe, so our prices have been significantly impacted by the yen to euro exchange rate.

When we set our previous forecast, the exchange rate was set at 160 yen per euro, but since there have been times in the first half of 2024 when the euro has topped 175 yen, we have set that as the exchange rate in our revised forecast.

As of today (August 2), the exchange rate is around 160 yen per euro; if this trend (of around 160 yen per euro) continues, our revised exchange rate assumptions are conservative.

**Question 3**

What does “the impact of increased volume” mean in the list of factors influencing the increase in sales costs?

**Answer 3 (Kondo)**

The impact of increased volume refers to how much the cost of sales would increase if the unit price and exchange rate were unchanged.

**Question 4**

You said that pollen collection to increase the production of CEDARCURE is proceeding as planned.

I would like you to provide more detail quantitatively about how much you plan to collect, how much has been collected, and how much increase in production is expected to come from the collected amount in how many years.

Further, in the forecast for 2025 that you plan to present at the close of fiscal 2024, please also provide a sales forecast and your thoughts for 2026 and beyond, in addition to a sales forecast for 2025.

**Answer 4 (Matsuda)**

This is a qualitative explanation, but last year we established a Source Materials Procurement Department, and this has strengthened our efforts in pollen collection. We have been able to collect even more from businesses that we already work with. We have also secured cooperation agreements with a number of new businesses, so we expect even better results in the coming years.

Looking ahead, with the pollen collection situation, after carefully assessing this expansion of manufacturing facilities, we will determine the exact timing for the easing of shipment limits.

As for what will be communicated when we announce our 2024 financial results, we would like to take into consideration the requests we have received when responding.

Finally, we are making steady progress on necessary initiatives, including capital investment.

**Question 5**

I understand that there are aspects of CEDARCURE’s future that are easy to predict and aspects that aren’t. Beyond just sales targets, I believe it would be helpful to show what is and isn’t certain through supplemental explanations. This would help promote understanding, so please consider doing this in the future.

**Answer 5 (Matsuda)**

Understood.

**Question 6**

In the first half of the year in the skin disease area, sales of CORECTIM, ANTEBATE, and LOCOID all did well. Can you tell us more about the factors that allowed for this?

In the revised forecast, you have also revised your sales forecast for CORECTIM down. Does “cannibalization” by VTAMA<sup>®</sup> play any role in this?

**Answer 6 (Kondo)**

First, ANTEBATE is a steroid drug that has been used widely and for a long time as a treatment for atopic dermatitis. Since the price of ANTEBATE is now the same as its generic counterparts, many more people are choosing to use the non-generic form of the drug. Thus, it is performing well. Consequently, we believe the reason that ANTEBATE sales volume is firm has little to do with CORECTIM or VTAMA<sup>®</sup>, both of which are non-steroidal drugs.

Next, CORECTIM is a non-steroidal drug. For a long time, the only treatments for atopic dermatitis have been steroids and tacrolimus ointment. CORECTIM is positioned as a new option different from either. Other companies have also released medications that are neither steroids nor tacrolimus, and the non-steroid market is growing since the new drugs are free of side effects seen with steroids and tacrolimus. CORECTIM is also growing within that market. While VTAMA<sup>®</sup> is also a non-steroidal drug, it has a different action mechanism than CORECTIM. Symptoms in patients with atopic dermatitis vary, so one medication will not suffice for all cases.

In instances like this, being able to consult with a doctor about the various available options when choosing the appropriate treatment and medication greatly benefits the patients. This ultimately leads to increased sales for the Company. In that sense, there is significant meaning in having more options become available.

We believe that some degree of “cannibalization” will occur between the two non-steroidal drugs CORECTIM and VTAMA<sup>®</sup>, and our sales forecasts were prepared taking this into account.

**Question 7**

While the sales for ANTEBATE in the first half of the year have grown by a double-digit percentage point over this time last year, in the revised forecast, growth is shown at a single-digit percentage point. Can you please explain why growth appears to weaken in the second half?

**Answer 7 (Kondo)**

We believe that the sales volume of ANTEBATE in the first half of the year increased due to the switch from generic drugs by patients. But since we do not believe that this switch will continue at the same pace going forward, we have prepared a revised forecast taking past and future trends into account.

**Question 8**

With the revised forecast, if we added together the sales of CORECTIM and VTAMA<sup>®</sup>, how much growth do you expect to see? Can we think of this total as positive overall?

**Answer 8 (Kondo)**

If we add CORECTIM and VTAMA<sup>®</sup>, naturally the total will be positive. We do not think that we will launch VTAMA<sup>®</sup> and then see CORECTIM largely replaced by it.

**Question 9**

When the expanded manufacturing facilities for CEDARCURE go online as expected during 2025, how much CEDARCURE will you be able to produce?

**Answer 9 (Matsuda)**

As we explained, we decided to invest approximately ¥3 billion in facilities to manufacture active pharmaceutical ingredients. Once the facilities have come online, we expect to be able to deliver CEDARCURE to 500,000 patients annually, but another important question is how much cedar pollen we can secure. We will keep closely monitoring demand forecasts and consider further capital investments accordingly.