



TORII PHARMACEUTICAL CO., LTD.

【Event Summary】

Company Name : TORII PHARMACEUTICAL CO., LTD

Company ID : 4551

Event Type : Earnings Announcement

Fiscal Period : FY2023 Annual

Date : February 14, 2024

Time : 11:00 AM–12:00 Noon

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

Venue : Webcast

Number of Speakers : 2

Goichi Matsuda Representative Director,

President and Chief Executive Officer

Nobumasa Kondo Senior Executive Officer



Financial Results Briefing for the Fiscal Year Ended December 31, 2023

February 14, 2024

 TORII PHARMACEUTICAL CO., LTD.



Financial Results for FY 2023 and Financial Forecasts for FY2024

Nobumasa Kondo,
Senior Executive Officer

My name is Kondo. I am a Senior Executive Officer of TORII PHARMACEUTICAL.

I will explain the financial results for fiscal year 2023 and the financial forecasts for fiscal year 2024.

AGENDA

- **Financial Results for FY2023**
- Financial Forecasts for FY2024
- Remarks

First is the financial results for fiscal year 2023.

Please look at slide 4.

Financial Results for FY2023

- Achieved double-digit percentage growth in net sales and operating income before deduction of R&D expenses, which are numerical indicators for the Medium-Term Management Plan 2023-2025
- Net sales and each income indicator surpassed the previous forecasts

(Millions of JPY)	vs. FY2022		vs. Previous Forecast		vs. FY2022	
	FY2023	(Abs)	(%)	(abs)		(%)
Net sales	54,638	+5,742	+11.7%	+638	+1.2%	Net sales <ul style="list-style-type: none"> • Double-digit growth driven by the allergens area and the skin disease area
Gross profit	24,791	+1,412	+6.0%	+91	+0.4%	Operating income <ul style="list-style-type: none"> • Decreased mainly due to higher cost of sales resulting from higher purchasing unit prices and negative FX impact, as well as higher SG&A expenses • R&D expenses are significant higher due to one-time payment (approx. ¥1.6 billion) for in-licensed drugs from Nogra Pharma Ltd
Operating income	5,035	-604	-9.1%	+535	+11.9%	Operating income before deduction of R&D expenses <ul style="list-style-type: none"> • Increased driven by top-line growth coupled with SG&A expenses (exc. R&D expenses) remaining same level with PY, despite the higher cost of sales
Operating income before deduction of R&D expenses	8,526	+1,324	+18.4%	+426	+5.3%	Net income <ul style="list-style-type: none"> • Increased mainly due to gains on sales of cross-shareholdings, despite a decline in operating income
Net income	4,119	+175	+4.4%	+719	+21.1%	
(Reference) R&D expenses	3,490	+1,829	+110.1%	-110	-3.1%	

Our company has set "net sales" and "operating income before deduction of R&D expenses" as numerical indicators in our Medium-Term Management Plan. Even in the severe business environment of rising raw material costs and the depreciation of the yen, we achieved double-digit percentage growth from the previous year in both of these indicators. With regards to the factors behind the year-on-year changes in each category, firstly, net sales increased by 11.7% compared to the previous year due to growth in the allergens area and the skin disease area. The details of the net sales in each of these areas are described on the following pages.

Next, regarding operating income, there was a decrease of 9.1% year on year due to various factors. This included a higher cost of sales resulting from higher purchasing unit prices and negative foreign exchange impact, and also a large increase in R&D expenses due to the one-time payment of around ¥1.6 billion to Nogra Pharma Ltd. in January 2023 for in-licensed drugs.

Regarding operating income before deduction of R&D expenses, despite the situation of the higher cost of sales, an increase of 18.4% year on year was realized due to the top-line growth.

Regarding net income, although operating income declined, net income increased 4.4% year on year, mainly due to gains on sales of cross-shareholdings and a decrease in corporation tax.

In comparison with the previous forecast, the results for net sales and each income indicator surpassed the previous forecasts.

Renal Disease and Hemodialysis Area / Skin Disease Area

- Renal diseases and hemodialysis: Almost same level with FY driven by growth in Riona despite a decline in REMITCH
- Skin diseases: Increased by 15.1% driven by CORECTIM and ANTEBATE

Renal diseases & hemodialysis

(Millions of JPY)	FY2023	vs. FY2022 (abs)	vs. FY2022 (%)
Total Net Sales	11,888	-124	-1.0%
- Riona	7,515	+575	+8.3%
- REMITCH	2,725	-811	-22.9%
- Other	1,647	+112	+7.2%

Riona

- Increased by 8.3% as higher sales volume from the spread of prescriptions for iron deficiency anemia outweighed the negative impact of NHI drug price revisions

REMITCH

- Decreased by 22.9% due to lower sales volume resulting from the negative impact of NHI drug price revisions coupled with the impact of generic products

Skin diseases

(Millions of JPY)	FY2023	vs. FY2022 (abs)	vs. FY2022 (%)
Total Net Sales	14,266	+1,874	+15.1%
- CORECTIM	7,450	+1,981	+36.2%
- ANTEBATE	4,533	+538	+13.5%
- Other	2,281	-643	-22.0%

CORECTIM

- Increased by 36.2% driven by higher sales volume including formulations with pediatric indication

ANTEBATE

- Increased by 13.5% primarily driven by higher sales volume mainly resulting from a switch from generic products

Next, I will explain the net sales in each area.

Please look at slide 5.

First is the renal disease and hemodialysis area.

Although Riona was impacted by the negative NHI drug price revisions, an increase of 8.3% year on year was achieved due to an increase in sales volume from the spread of prescriptions for iron deficiency anemia.

With regards to REMITCH, in addition to the impact of the negative NHI drug price revisions, there was also a lower sales volume due to growth in generic products, and the net sales decreased 22.9% year on year.

As a result, net sales in the renal disease and hemodialysis area were almost at the same level as the previous year.

Next is the skin disease area.

Net sales of CORECTIM increased by 36.2% year on year due to an increase in sales volume, including formulations with pediatric indication.

For ANTEBATE, net sales increased 13.5% year on year, mainly because the elimination of the difference in price from generic products led to a switching from the generic products and an increased sales volume.

Net sales for other skin disease products decreased by 22.0% year on year, mainly due to the transfer of the Dovonex treatment for psoriasis vulgaris, to LEO Pharma in January 2023.

As a result, net sales in the skin disease area increased significantly by 15.1% year on year.

Allergens Area / Other Area

- Allergens: Increased by 17.2% driven by further spread of allergen immunotherapy
- Other: Increased by 14.9% driven by ORLADEYO and BIO-THREE

Allergens			
(Millions of JPY)	FY2023	vs. FY2022 (abs)	vs. FY2022 (%)
Total Net Sales	21,685	+3,185	+17.2%
- CEDARCURE	11,356	+1,748	+18.2%
- MITICURE	10,148	+1,454	+16.7%
- Other	179	-16	-8.6%

Other			
(Millions of JPY)	FY2023	vs. FY2022 (abs)	vs. FY2022 (%)
Total Net Sales	6,498	+840	+14.9%
- BIO-THREE	4,041	+680	+20.3%
- ORLADEYO	1,546	+233	+17.7%
- Other	910	-73	-7.5%

CEDARCURE

- Increased by 18.2% driven by a higher number of new patients through the spread of allergen immunotherapy
- Limited shipments are expected to continue in 2024

MITICURE

- Increased by 16.7% driven by higher sales volume resulting from the rise in the number of new patients

BIO-THREE

- Increased by 20.3% driven by expansion of the intestinal regulation market coupled with the positive impact of NHI drug price revisions

ORLADEYO

- Increased by 17.7% driven by an increase in the number of new patients

Next, I will explain the results in the allergens area and the other area.

Please look at slide 6.

First, the allergens area.

Net sales of CEDARCURE increased by 18.2% year on year, driven by a higher number of new patients through the spread of allergen immunotherapy.

Although there continues to be significant demand, supply is currently not keeping pace with that demand. We are currently making limited shipments of the drug for new patients, and it is expected that these limited shipments will continue in 2024.

I apologize sincerely for the inconvenience this is causing.

As with CEDARCURE, the net sales of MITICURE were also driven by the continuing increase in the number of new patients due to the spread of allergen immunotherapy, resulting in a 16.7% increase in net sales year on year.

In the overall results, net sales in the allergens area increased significantly by 17.2% year on year.

Next is the other area.

Net sales of BIO-THREE increased by 20.3% year on year. This was due to an increased sales volume driven by expansion of the intestinal regulation market, coupled with the positive impact of NHI drug price revisions.

ORLADEYO is a growth-stage product and net sales increased by 17.7% year on year, driven by an increase in the number of new patients.

As a result, net sales in the other area increased by 14.9% year on year.

Roadmap of Operating Income Before Deduction of R&D Expenses variance

- Achieved the upper 10% range growth driven by an increase in net sales coupled with efficient investment partially offset by higher cost of sales

Roadmap of Operating Income Before Deduction of R&D Expenses variance



Next, I will explain the roadmap of operating income before deduction of R&D expenses variance.

Please look at slide 7.

Net sales increased by approximately 5.7 billion yen, driven by the allergens area and the skin disease area. On the other hand, the cost of sales increased significantly by approximately 4.3 billion yen year on year, due to a higher purchasing unit price and a negative foreign exchange impact. As a result, although the gross profit increased year on year, the increase was only approximately 1.4 billion yen, which is 6.0%.

With regards to the SG&A expenses excluding R&D expenses, even in the context of an increase in business volume, the result remained at the same level as in the previous fiscal year due to the efficient execution of expenses.

As a result, the operating income before deduction of R&D expenses increased by approximately 1.3 billion yen, or 18.4 percent, year on year.

AGENDA

- Financial Results for FY2023
- **Financial Forecasts for FY2024**
- Remarks

This concludes the explanation of our financial results for fiscal year 2023.

From the next slide, I will explain the financial forecasts for fiscal year 2024.

Financial Forecasts for FY2024

- Net sales are expected to increase by 7.3% as continuous growth in the skin disease area and the allergens area
- Operating income before deduction of R&D expenses is expected to increase by 8.5% driven by top-line growth, despite higher cost of SG&A expenses

(Millions of JPY)	FY2024	vs. FY2023 (abs)	vs. FY2023 (%)	vs. FY2023
Net sales	58,600	+3,961	+7.3%	Net sales • Expected to increase by 7.3% driven by skin disease area and allergens area
Gross profit	26,500	+1,708	+6.9%	Operating income • Expected to increase by 15.2% driven by higher net sales, despite an increase in cost of sales and SG&A expenses due to higher purchasing unit price and negative FX impact • R&D expenses are expected to be same level as 2023 (+) higher costs for new drug developments (-) favorable comparison of the expense vs. the one recorded in 2023 for in-licensed drugs from Nogra Pharma Ltd
Operating income	5,800	+764	+15.2%	Operating income before deduction of R&D expenses • Expected to increase by 8.5% driven by an increase in net sales, partially offset by higher cost of sales and SG&A expenses
Operating income before deduction of R&D expenses	9,250	+723	+8.5%	Net income • Expected to increase by 14.1% due to an increase in operating income, partially offset by unfavorable comparison of the gains vs. the one recorded in 2023 for the sale of cross-shareholdings
Net income	4,700	+580	+14.1%	
(Reference) R&D expenses	3,450	-40	-1.2%	

Net sales are expected to increase by 7.3% year on year due to the continuous growth in the allergens area and the skin disease area.

For operating income, although it is expected that the cost of sales and SG&A expenses will increase due to the higher purchasing unit price and negative foreign exchange impact continuing from the previous year, operating income is expected to increase 15.2% year on year due to higher net sales.

With regards to R&D expenses, although there will not be the one-time payment of around ¥1.6 billion recorded in fiscal year 2023 for in-licensed drugs from Nogra Pharma Ltd., the R&D expenses are expected to remain at the same level as the previous year due to higher costs for new drug developments.

Regarding operating income before deduction of R&D expenses, it is expected that an increase in net sales will drive an increase of 8.5% year on year despite expected increases in the cost of sales and SG&A expenses.

For net income, an increase of 14.1% is expected due to an increase in operating income, even though this will be partially offset by unfavorable comparison of the gains vs. the one recorded in 2023 for the sale of cross shareholdings.

Renal Disease and Hemodialysis Area / Skin Disease Area

- The renal disease and hemodialysis area is expected to decline, despite enhancing further penetration of Riona and ENAROY
- The skin disease area is expected to grow significantly driven by further growth of CORECTIM and new launch of JTE-061

Renal diseases & hemodialysis

(Millions of JPY)	FY2024	vs. FY2023 (abs)	vs. FY2023 (%)
Total Net Sales	10,020	-1,868	-15.7%
- Riona	6,700	-815	-10.8%
- REMITCH	1,830	-895	-32.9%
- Other	1,490	-158	-9.6%

Riona

- Expected to decrease by 10.8% due to the negative impact of NHI drug price revisions and the expected launch of generic products

REMITCH

- Expected to decrease by 32.9% due to the negative impact of NHI drug price revisions and the expected growth of generic products

Skin diseases

(Millions of JPY)	FY2024	vs. FY2023 (abs)	vs. FY2023 (%)
Total Net Sales	17,060	+2,793	+19.6%
- CORECTIM	8,800	+1,349	+18.1%
- ANTEBATE	4,770	+236	+5.2%
- Other	3,490	+1,207	+52.9%

CORECTIM

- Expected to increase by 18.1% driven by higher sales volume including formulations with pediatric indication

Other

- New launch of JTE-061 within 2024 etc. are expected

Next, I will explain the financial forecasts for each area.

Please look at slide 10.

First is the renal disease and hemodialysis area.

Net sales for Riona are expected to decrease by 10.8% year on year due to the negative impact of NHI drug price revisions and taking into account a decrease in sales volume due to the expected launch of generic products in 2024. Net sales of REMITCH are expected to decrease by 32.9% year on year due to the negative impact of NHI drug price revisions and the expected further growth of generic products.

As a result, the net sales in the renal disease and hemodialysis area are expected to decrease by 15.7% year on year.

Next is the skin disease area.

For CORECTIM, net sales are expected to increase by 18.1%, driven by a higher sales volume, including formulations with pediatric indication.

With regards to the other item, a significant increase of 52.9% is expected year on year as a result of forecasts such as "the 2024 launch of JTE-061, for which an application was filed for approval of manufacturing and sales for indications of atopic dermatitis and psoriasis vulgaris".

As a result, net sales in the skin disease area are expected to increase significantly, by 19.6% year on year.

Allergens Area / Other Area

- The Allergens area is expected to continue gaining momentum to record nearly 10% growth
- The Other area is expected to grow significantly with the growth of BIO-THREE and ORLADEYO Capsules

Allergens			
(Millions of JPY)	FY2024	vs. FY2023 (abs)	vs. FY2023 (%)
Total Net Sales	23,790	+2,104	+9.7%
- CEDARCURE	12,610	+1,253	+11.0%
- MITICURE	11,020	+871	+8.6%
- Other	160	-19	-11.1%

Other			
(Millions of JPY)	FY2024	vs. FY2023 (abs)	vs. FY2023 (%)
Total Net Sales	7,450	+951	+14.6%
- BIO-THREE	4,400	+358	+8.9%
- ORLADEYO	2,270	+723	+46.7%
- Other	780	-130	-14.3%

CEDARCURE

- Expected to increase by 11.0% despite limited shipments, which are expected to continue throughout 2024

MITICURE

- Expected to increase by 8.6% with further spread of allergen immunotherapy

BIO-THREE

- Expected to increase by 8.9% driven by higher sales volume resulting from further expansion of the intestinal regulation market

ORLADEYO

- Increased by 46.7% driven by an increase in the number of new patients

Next, I will explain the financial forecasts for the allergens area and the other area.

Please look at slide 11.

First is the allergens area.

For CEDARCURE, although the limited shipments are expected to continue throughout 2024, it is predicted that an increase in the sales volume will drive a net sales increase of 11.0% year on year.

Our efforts to increase production include the establishment in August 2023 of a department to specialize in the collection of cedar pollen, which is used as a raw material, and we are working to increase the amount of cedar pollen collected. We are also working to expand our production line for the drug substance manufacturing and those operations are scheduled to start in 2025.

President and Chief Executive Officer Matsuda will be giving a detailed explanation of the future outlook for CEDARCURE and our efforts to increase production later.

As with CEDARCURE, the net sales of MITICURE are expected to increase 8.6% year on year due to the further spread of allergen immunotherapy.

As a result, the net sales in the allergens area are expected to increase by 9.7% year on year.

Next is the other area.

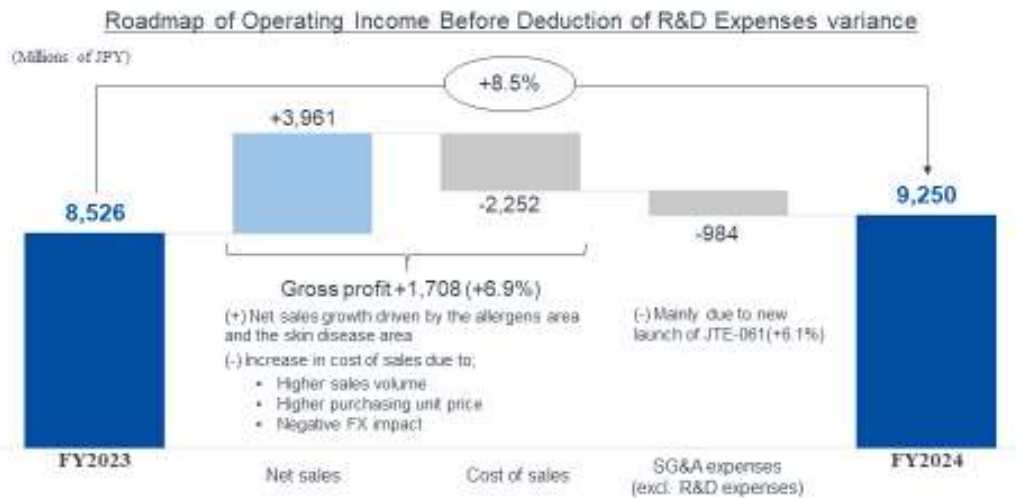
For BIO-THREE, as further expansion of the intestinal regulation market is expected, net sales are expected to increase by 8.9% year on year.

ORLADEYO will continue to be a growth-stage product and it is expected that there will be an increase in the number of new patients that drives a net sales increase of 46.7% year on year.

As a result, the net sales in the other area are expected to increase by 14.6% year on year.

Roadmap of Operating Income Before Deduction of R&D Expenses variance

- Operating income before deduction of R&D expenses is expected to increase by 8.5% vs. PY driven by an increase in net sales, partially offset by higher cost of sales and an increase in SG&A expenses due to the new launch of JTE-061



Next is the roadmap of operating income before deduction of R&D expenses variance in the financial forecast. Please look at slide 12.

Net sales are expected to increase by approximately 3.9 billion yen year on year due to the continuous growth in the allergens area and the skin disease area.

On the other hand, the cost of sales is expected to increase significantly again in 2024 due to higher purchasing unit prices and a negative foreign exchange impact. As a result, the gross profit is only expected to increase by approximately 1.7 billion yen, or 6.9 percent, year on year.

The SG&A expenses excluding R&D expenses are expected to increase by approximately 0.9 billion yen, or 6.1%, year on year, mainly due to aggressive promotional activities planned in conjunction with the launch of JTE-061.

As a result, the operating income before deduction of R&D expenses is expected to increase by approximately 0.7 billion yen, or 8.5%, driven by an increase in net sales, but partially offset by a higher cost of sales and an increase in SG&A expenses due to the new launch of JTE-061.

AGENDA

- Financial Results for FY2023
- Financial Forecasts for FY2024
- **Remarks**

Finally, please look at slide 14.

Remarks

Results for FY2023

- ✓ Achieved strong growth of double-digit percentage increases in net sales and operating income before deduction of R&D expenses, despite the challenging business environment
- ✓ Steady progress to realize the Medium-/Long-Term Business Vision "VISION2030"

Forecasts for FY2024

- ✓ Expected an increase in net sales driven by further growth of skin disease and allergens areas which are growth drivers for realizing "VISION2030", despite the business environment is expected to remain tough
- ✓ Achieve profit growth through top-line growth despite further cost increases

Shareholder returns

- ✓ Annual dividend per share (planned)
 - FY2023: JPY 120
 - FY2024: JPY 120

This is a summary of what I have said so far. First, in the results for fiscal year 2023, we achieved strong growth of double digit percentage increases in net sales and operating income before deduction of R&D expenses, despite the challenging business environment. It was a year when we made steady progress to realize our Medium-/Long-Term Business Vision "VISION2030."

In fiscal year 2024, although the business environment is expected to remain tough, we forecast an increase in net sales driven by further growth in the skin disease and allergens areas, which are growth drivers for realizing "VISION2030."

Although further cost increases are expected, we forecast continued profit growth through this increase in net sales.

Finally, I would like to explain the shareholder returns.

We plan to pay an annual dividend of 120 yen per share for fiscal year 2023.


We also plan 120 yen as our forecast for the annual dividend per share for fiscal year 2024.

President and Chief Executive Officer Matsuda will explain our shareholder return policy and thinking on dividends in fiscal year 2023 and 2024 later.

This is the end of my explanation. Thank you very much.

The Medium-Term Management Plan 2024-2026

Goichi Matsuda,
Representative Director,
President and Chief Executive Officer

 TORII PHARMACEUTICAL CO., LTD.

My name is Matsuda. I am President and Chief Executive Officer of TORII PHARMACEUTICAL.

My explanation will mainly focus on our Medium-Term Management Plan 2024-2026.

AGENDA

- **Progress in 2023 toward the Medium-Term Management Plan 2023-2025**
- Medium-/Long-Term Business Vision "VISION2030"
- The Medium-Term Management Plan 2024-2026
- Enhancement of corporate value

As shown here, I will first explain the progress of the Medium-Term Management Plan 2023-2025 and then proceed through our Medium-/Long-Term Business Vision "VISION2030," the Medium-Term Management Plan 2024-2026," and finally our enhancement of corporate value.

First is details of our progress toward the Medium-Term Management Plan 2023-2025.

Progress in 2023 toward the Medium-Term Management Plan 2023-2025 –Numerical Indicators–

- The numerical indicators set forth at the time of formulation of the Medium-Term Management Plan 2023-2025 are as follows:

Initial plan for FY2023	Guidance for FY2025 ²	What VISION2030 aims for
Net sales	Net sales	Net sales
¥50.9 billion	¥54.0 – 57.0 billion	Net sales break the all-time high ³
Operating income (before deduction of R&D expenses) ¹	Operating income (before deduction of R&D expenses) ¹	Operating income ⁴
¥7.6 billion	¥9.0 – 10.0 billion	Operating income comes within the range of breaking the all-time high ⁴

*1: We actively invest in R&D for the time being, in order to obtain in-licensed drugs in the future. For this reason, Torii sets operating income before deduction of R&D expenses as a numerical income indicator for the Medium-Term Management Plan.

*2: A reference value that represents a rough estimate for Torii at this point in time and is not positioned as a target to be achieved.

*3: All-time high net sales: ¥64.1 billion (fiscal year ended December 31, 2017)

*4: Although we will continue to invest in R&D beyond 2030, we expect to have completed our intensive investment to a certain extent. For this reason, Torii sets operating income as an indicator for numerical targets of VISION2030. All-time high operating income: ¥13.3 billion (fiscal year ended March 31, 2001).

The numerical indicators set forth at the time of formulation of the Medium-Term Management Plan 2023-2025 are as shown.

Progress in 2023 toward the Medium-Term Management Plan 2023-2025 –Numerical Indicators–

- Achieved the initial plan through both net sales and operating income surpassed it driven by higher sales volume coupled with a decrease in SG&A expenses due to efficient execution.

	Initial plan for FY2023	Results for FY2023	FY2023 results compared to initial plan
Net sales	¥50.9 billion	¥54.6 billion	+ ¥3.7 billion
Operating income (before deduction of R&D expenses)	¥7.6 billion	¥8.5 billion	+ ¥0.8 billion

As stated earlier by Kondo, we have set net sales and the operating income before deduction of R&D expenses as indicators. For both of these, the results in the financial results for fiscal year 2023 exceeded the initial plan.

Progress in 2023 toward the Medium-Term Management Plan 2023-2025 –Major Initiatives–

Growth strategy

- ✓ Spread, cultivate, and maximize the value of new drugs in the growth phase
 - Renal diseases and hemodialysis: ENAROY, Riona
 - Skin diseases: CORECTIM
 - Allergens: CEDARCURE, MITICURE
 - ORLADEYO
- ✓ Promote new drug development
 - JTE-061
 - TO-208
- ✓ Reinforce in-licensing systems
- ✓ Maintenance of human resource systems in line with management strategies and work-style reforms
- ✓ Corporate culture reform

Maintaining the credibility of stakeholders

- ✓ Improve and strengthen stable supply systems
- ✓ Compliance with pharmaceutical regulations and quality assurance
- ✓ Reinforce compliance
- ✓ Reinforce corporate governance
- ✓ Initiatives on sustainability

As shown here, our major initiatives for our Medium-Term Management Plan are being advanced with the two pillars of growth strategy and maintaining the credibility of stakeholders.

Progress in 2023 toward the Medium-Term Management Plan 2023-2025 –Key Topics–

Growth strategy

- ✓ Steady growth in net sales of new drugs in the growth phase
 - Double-digit year-on-year growth in numerical indicator of net sales
- ✓ Favorable progress in development of JTE-061
 - Began Phase III clinical study in pediatric patients with atopic dermatitis (children ages 2 years or older and under 12 years old) in Japan (August 2023)
 - Japan Tobacco Inc. (JT) filed application for approval of manufacturing and sales in Japan for indications of atopic dermatitis and psoriasis vulgaris (September 2023)
- ✓ Favorable progress in development of TO-208
 - Announced the top-line results of Phase III clinical study for indications of molluscum contagiosum in Japan (December 2023)
- ✓ Obtained new in-licensed drugs
 - Skin disease treatment drug : NAC-GED-0507 (January 2023)
 - Allergen immunotherapy drug for grass pollinosis : GRAZAX (December 2023)

Maintaining the credibility of stakeholders

- ✓ Stable supply of CEDARCURE
 - Government request concerning cedar pollinosis (May 2023)
 - Established the Source Materials Procurement Dept. as a new department centrally responsible for cedar pollen procurement (August 2023)
 - Decided on capital investment in drug substance manufacturing equipment (scheduled to begin operations in 2025)
- ✓ Reinforce corporate governance
 - Resolved to transition to a company with an Audit and Supervisory Committee at the Board of Directors, subject to approval at the General Meeting of Shareholders to be held in March 2024 (November 2023)
- ✓ Initiatives on sustainability
 - Formulation of the Basic Policy on Sustainability, identification of materiality, and external announcement (February 2023)
 - Organize links between materiality and business strategies, major initiatives of the Medium-Term Management Plan, etc.

I will explain the key topics that are results of our efforts in major initiatives in fiscal year 2023.

For the growth of new drugs in the growth phase, (as Kondo also mentioned earlier) there was steady growth and we achieved double-digit year-on-year growth in the numerical indicator of net sales.

There was also favorable progress for JTE-061 and TO-208, which are currently in development. For JTE-061, we started Phase III clinical study in Japan in pediatric patients with atopic dermatitis, and Japan Tobacco Inc. (JT) filed an application for the approval of manufacturing and sales in Japan for indications of atopic dermatitis and psoriasis vulgaris. In addition, for TO-208, we obtained good top-line results from the Phase III clinical study in Japan.

With regards to new in-licensed drugs, two new drugs were obtained in fiscal year 2023. In addition to a skin disease treatment drug from Nogra Pharma, we also concluded a licensing agreement with ALK with respect to the exclusive development and commercialization in Japan of GRAZAX, an allergen immunotherapy drug for grass pollinosis. We will continue to expand our development pipeline through aggressive business investment.

I will explain in detail later about maintaining the credibility of stakeholders, but I recognize that steady progress has also been made in this area.

Progress in 2023 toward the Medium-Term Management Plan 2023-2025 –Major Investments–

- Decided on the following investment in FY2023 (expecting business investments of approx. JPY 40.0 BN in the five years until the end of 2027)

Major investments that have been decided*

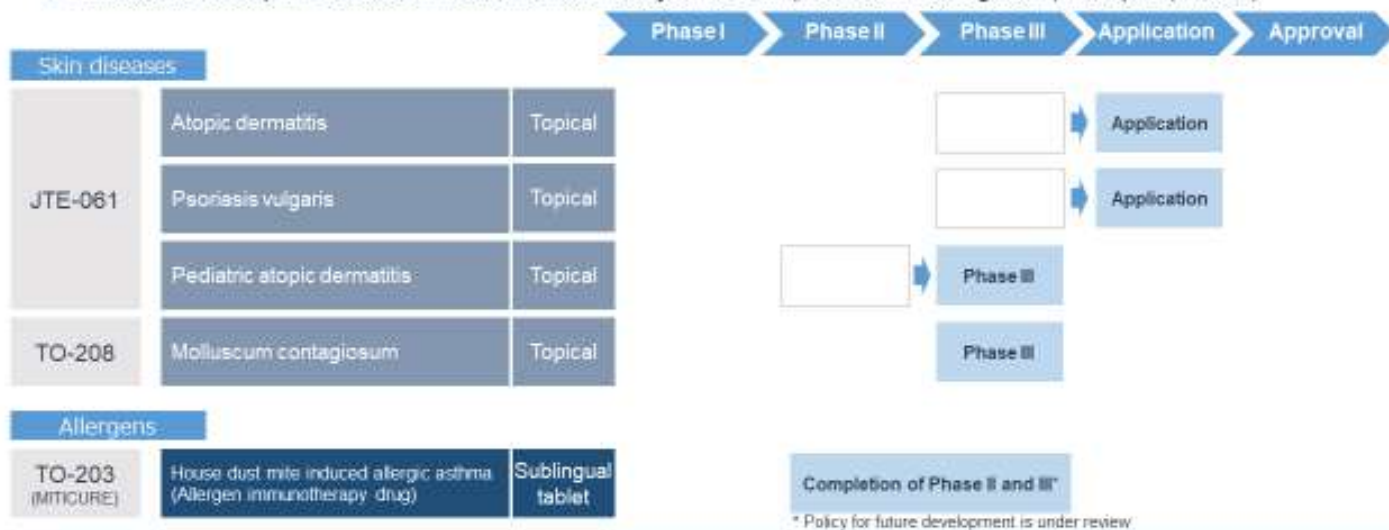
- ✓ License agreement for skin disease treatment drug (NAC-GED-0507)
 - Investment amount in FY2023: Approx. ¥1.6 billion
 - License agreement with respect to the exclusive development and commercialization of skin disease treatment drug (NAC-GED-0507) in Japan
 - Milestone payments will be made in accordance with the progress of development, etc.
- ✓ License agreement for allergen immunotherapy drug for grass pollinosis (GRAZAX)
 - Milestone payments of approx. ¥2.0 billion will be made in accordance with the progress of development, etc.
- ✓ Capital investment toward strengthening production capacity of CEDARCURE
 - Investment amount decided: Approx. ¥3.0 billion
 - Capital investment in drug substance manufacturing in order to respond to increased sales volumes of CEDARCURE

* Only previously disclosed investments that were decided in 2023 are listed. Payment timing varies by project.

Our company views the five years from 2023 to 2027 as a period for concentrated business investment and is expecting to make business investments of approximately 40 billion yen. The major investments that we decided in fiscal year 2023 and have already disclosed are as shown here.

Reference: Development Pipeline

- Started Phase III clinical study of JTE-061 (pediatric atopic dermatitis) in Japan (Aug'23)
- Filed application for approval of manufacturing and sales of JTE-061 (atopic dermatitis, psoriasis vulgaris) in Japan (Sep' 23)
- Announced the top-line results of Phase III clinical study of TO-208 (molluscum contagiosum) in Japan (Dec'23)



The status of our pipeline is as shown.

As mentioned previously, in fiscal year 2023, progress was made in the development of JTE-061 and TO-208.

AGENDA

- Progress in 2023 toward the Medium-Term Management Plan 2023-2025
- **Medium-/Long-Term Business Vision “VISION2030”**
- The Medium-Term Management Plan 2024-2026
- Enhancement of corporate value

Next, I will explain our Medium-/Long-Term Business Vision “VISION2030.”

Updated Numerical Targets of "VISION2030"

- Based on the updated sales forecasts for existing products and JTE-061, and in light of our favorable progress in obtaining new in-licensed drugs and developing new drugs, as well as our forecast that we will be able to achieve the all-time high net sales ahead of schedule, we have upwardly revised net sales in "VISION2030," and for operating income, clearly indicated the fiscal year in which we expect to break the all-time high operating income

Before update	After update
What Torii aims for in 2030 To be a pharmaceutical company with presence: A company that has a deep understanding of the medical needs, leverages our expertise and impetus to co-create optimal solutions with all stakeholders, and delivers new, valuable pharmaceutical products to meet those needs.	What Torii aims for in 2030 (Remain unchanged)
Net sales Net sales break the all-time high (JPY 64.1 BN) ^{*1} Operating income Operating income comes within the range of breaking the all-time high (JPY 13.3 BN) ^{*2}	Net sales <u>Over JPY 80.0 BN</u> Operating income Operating income comes within the range of breaking the all-time high (JPY 13.3 BN) ^{*2} <u>in 2032</u>

*1: All-time high net sales: JPY 64.1 BN (fiscal year ended December 31, 2017)

*2: All-time high operating income: JPY 13.3 BN (fiscal year ended March 31, 2001)

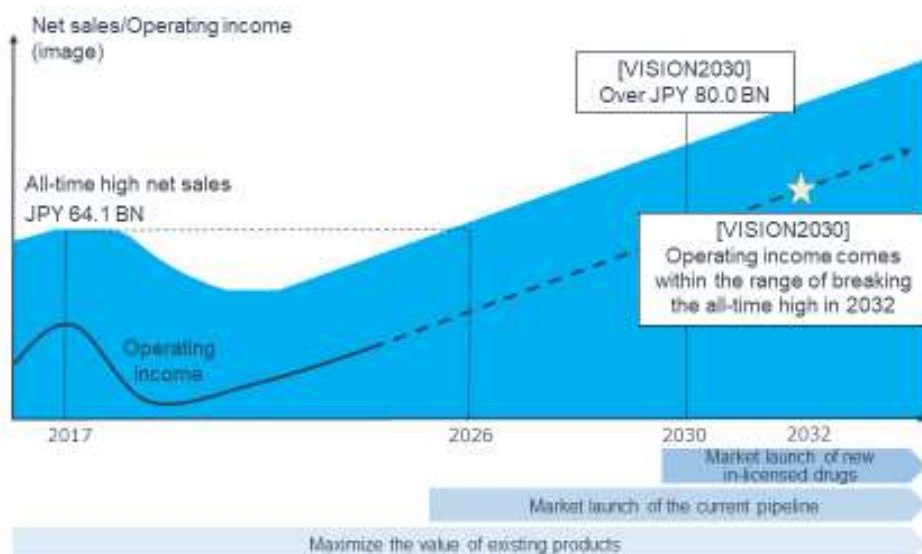
There are no changes to VISION2030 regarding what Torii aims for in 2030.

However, based on the updated sales forecasts for existing products and JTE-061, and in light of our favorable progress in obtaining new in-licensed drugs and developing new drugs, we now forecast that we will be able to achieve the all-time high net sales (64.1 billion yen) in fiscal year 2026.

Accordingly, we have upwardly revised the net sales target in "VISION2030" from net sales break the all-time high (64.1 billion yen) to net sales of over 80 billion yen. We will also update our target for operating income by clearly indicating the fiscal year in which operating income comes within the range of breaking the all-time high (13.3 billion yen). We have updated this target to operating income comes within the range of breaking the all-time high (13.3 billion yen) in 2032.

Medium-/Long-Term Business Vision “VISION2030”

- Towards greater heights than the past by overcoming fluctuations



This is the image of the trends in net sales and operating income toward VISION2030.

We aim to reach over 80 billion yen in net sales by 2030, which is around double the 41.7 billion yen level of net sales in fiscal 2020, which had the lowest sales in recent years. The assumption is that the majority of the sales in 2026 will be from the existing products and JTE-061, and that by 2030, the current pipeline will also have been launched and account for the majority of sales at that point. Going forward, we will continue working to expand our pipeline, but that will primarily be in investments for sustainable growth from 2030 onward. We are currently looking to achieve the numerical targets of VISION2030 with a certain degree of certainty in terms of both net sales and operating income.

AGENDA

- Progress in 2023 toward the Medium-Term Management Plan 2023-2025
- Medium-/Long-Term Business Vision "VISION2030"
- **The Medium-Term Management Plan 2024-2026**
- Enhancement of corporate value

Next, I will explain our Medium-Term Management Plan 2024-2026.

Outline of the Medium-Term Management Plan 2024-2026 –Numerical Targets and Guidance–

- Torii sets net sales and operating income before deduction of R&D expenses as numerical indicators for the Medium-Term Management Plan 2024-2026
- Achieve the initial net sales target for VISION2030 (all-time high net sales: ¥64.1 billion) in FY2026
- Operating income before deduction of R&D expenses in FY2026 is expected to be almost same level as in FY2025

Forecast for FY2024		Guidance for FY2026 ^{2, 3}		What VISION2030 aims for ³
Net sales	➔	Net sales	➔	Net sales
¥58.6 billion		¥63.0 – 66.0 billion		Over ¥80.0 billion
Operating income (before deduction of R&D expenses) ¹		Operating income (before deduction of R&D expenses) ¹		Operating income ⁴
¥9.2 billion		¥9.0 – 10.0 billion		Operating income comes within the range of breaking the all-time high ⁴ in 2032

*1: We actively invest in R&D for the time being, in order to obtain in-licensed drugs in the future. For this reason, Torii sets operating income before deduction of R&D expenses as a numerical income indicator for the Medium-Term Management Plan.

*2: A reference value that represents a rough estimate for Torii at this point in time and is not positioned as a target to be achieved.

*3: If CEDARCURE and MITICURE continue their recent net sales growth, they may be subject to market expansion repricing (drug price reduction) within the next few years. (This risk has been estimated to a certain extent and reflected in the guidance for FY2026 and VISION2030.)

*4: Although we will continue to invest in R&D beyond 2030, we expect to have completed our intensive investment to a certain extent. For this reason, Torii sets operating income as an indicator for numerical targets of VISION2030. All-time high operating income: ¥13.3 billion (fiscal year ended March 31, 2001)

First, as the numerical indicators, we have set net sales and operating income before deduction of R&D expenses as shown here.

The main reasons for the increase in the level of net sales compared to the fiscal year 2025 guidance were because we revised the sales forecasts for our existing products and because we added the expected sales of JTE-061. On the other hand, the reason for keeping the operating income level unchanged from the fiscal year 2025 guidance is because we have assumed to a certain extent that if CEDARCURE and MITICURE continue their recent net sales growth, they may be subject to market expansion repricing (drug price reduction) within the next few years, and this assumption has been reflected in the guidance.

Outline of the Medium-Term Management Plan 2024-2026 –Major Initiatives–

- Continue two pillars of “growth strategy” and “maintaining the credibility of stakeholders” due to no change of business environment as well as making good progress in major initiatives and financial results in FY2023

Growth strategy

- ✓ Spread, cultivate, and maximize the value of new drugs in the growth phase
 - Renal diseases and hemodialysis: ENAROY, Riona
 - Skin diseases: CORECTIM, JTE-061
 - Allergens: CEDARCURE, MITICURE
 - ORLADEYO
- ✓ Promote new drug development
 - TO-208
 - NAC-GED-0507
 - GRAZAX
- ✓ Obtain new in-licensed drugs
- ✓ Maintenance of human resource systems in line with management strategies and work-style reforms
- ✓ Corporate culture reform

Maintaining the credibility of stakeholders

- ✓ Improve and strengthen stable supply systems
- ✓ Compliance with pharmaceutical regulations and quality assurance
- ✓ Reinforce compliance
- ✓ Enhance corporate governance
- ✓ Initiatives on sustainability

With regards to the major initiatives, as we have made steady progress in both the major initiatives and financial results in fiscal year 2023, we will not make any major changes. We will continue to implement the two pillars of growth strategy and maintaining the credibility of stakeholders, and will work on each of the initiatives shown.

Outline of the Medium-Term Management Plan 2024-2026 –Major Initiatives–

- Spread, Cultivate, and Maximize the Value of New Drugs in the Growth Phase, and Promote New Drug Development

- Focusing on three areas; the renal disease and hemodialysis, the skin disease and the allergens
- Growth drivers for realizing VISION2030 are the skin disease area and the allergens area

Renal diseases and hemodialysis

- ✓ Achieve further market penetration for Riona with additional indications for iron deficiency anemia
- ✓ Achieve further market penetration for ENAROY, a growth-stage product launched in December 2020
- ✓ Provide a wide product lineup including REMITCH, by appropriately utilizing our accumulated knowledge and information in the renal disease and hemodialysis area

Skin diseases

- ✓ Focus on further market penetration of CORECTIM
- ✓ Work toward early market launch and market penetration of developed products* (JTE-061, TO-208, NAC-GED-0507)
- ✓ By adding developed products to our lineup alongside existing products, such as CORECTIM and ANTEBATE, address a wide range of diseases
- ✓ The role of growth drivers in achieving VISION2030

* Planned indications for developed products: JTE-061: atopic dermatitis, psoriasis vulgaris; TO-208: infectious conjunctivitis; NAC-GED-0507: skin disease

Allergens

- ✓ Aim for further growth of CEDARCURE and MITICURE
- ✓ For CEDARCURE, steadily work on efforts to ensure a stable supply in the future
- ✓ Implement the development of allergen immunotherapy drug for grass pollinosis (GRAZAX), which was in-licensed in December, for early market launch and market penetration
- ✓ The role of growth drivers in achieving VISION2030

I will now give an explanation for each of our franchise areas regarding the initiatives to spread, cultivate, and maximize the value of new drugs in the growth phase, and the initiatives to promote new drug development.

During the period of this Medium-Term Management Plan, we will continue to focus on the areas of renal disease and hemodialysis, skin disease and allergens.

In particular, we will position the skin disease area and the allergens area as growth drivers for realizing VISION2030, and we will strive to maximize the value of new drugs in the growth phase and to promote new drug development. The details are as shown on the slide.

Outline of the Medium-Term Management Plan 2024-2026 –Major Initiatives–

- Obtain New In-licensed Drugs

- Aggressively engage in exploration activities and business investments to enhance our development of pipeline through in-licensing
- Without limiting ourselves to the current franchise areas, aggressively take on the challenge of pursuing Torii Pharmaceutical's own in-licensing and development, including adjacent areas



With regards to initiatives to obtain new in-licensed drugs, we will continue to coordinate with JT and aggressively engage in exploration activities and business investments. However, we will also work to enhance our development pipeline by not limiting ourselves to the current franchise areas, and aggressively taking on the challenge of pursuing TORII PHARMACEUTICAL's own in-licensing and development, including in adjacent areas.

Outline of the Medium-Term Management Plan 2024-2026 –Major Initiatives–

- Strengthen Supply Chain to Ensure a Stable Supply of CEDARCURE

Status of limited shipments of CEDARCURE (introduction dose)

- ✓ Continuing to receive introduction dose orders far above our expectations
- ✓ Limited shipments of introduction doses to ensure a stable supply of maintenance doses
*Maintenance doses are not subject to limited shipments, and there is no problem with stable supply to a certain number of new patients and patients who have already started taking or who continue taking the drug.
- ✓ We expect that it will take until 2025 before we can significantly increase both the cedar pollen collection volume, which is a raw material, and the drug substance production volume. Limited shipments are therefore expected to continue in 2024

Summary of government request concerning cedar pollinosis

- ✓ Overall picture of the government's pollinosis countermeasures (ministerial meeting concerning pollinosis)
 - Regarding the treatment of pollinosis, it was determined that the government shall "start to request cooperation from forest associations, etc. and companies, with the aim of increasing production of therapeutic drugs for sublingual immunotherapy from drugs for 250,000 people per year to 1 million people per year within five years"
- ✓ The Ministry of Health, Labour and Welfare requested the Company to "respond to meet market demand through increased production, etc." and "implement measures necessary to ensure a stable supply of products in the future"

As part of our efforts to improve and strengthen stable supply systems, I will now explain our efforts to achieve a stable supply of CEDARCURE cedar sublingual tablets.

There are two different types of CEDARCURE, which are the introduction dose and the maintenance dose, which provide different dosages depending on the time of administration. We are currently limiting our shipments of the introduction dose.

The background to this limited shipment was that in February and March 2023, we continued to receive introduction dose orders that were far above our expectations. We started to limit shipments of the introduction doses in order to ensure a stable supply of maintenance doses for patients who are already taking the drug and for patients who will start taking the drug. In other words, the maintenance doses are not subject to limited shipments, and the limited shipments of introduction doses mean that there is no problem with stable supply to a certain number of new patients and patients who have already started taking or who continue taking the drug.

In addition, we expect that it will take until 2025 before we can significantly increase both the cedar pollen collection volume, which is a raw material, and the drug substance production volume, so limited shipments are expected to continue in 2024.

Although this is not a direct cause of the limited shipment, the summary of the government request concerning cedar pollinosis is as shown here.

Outline of the Medium-Term Management Plan 2024-2026 –Major Initiatives– - Strengthen Supply Chain to Ensure a Stable Supply of CEDARCURE

Status of efforts to ensure a stable supply

- ✓ With the establishment of the Source Materials Procurement Dept. in August 2023, we have started planning and execution of a new collection scheme aimed at dramatically increasing our cedar pollen collection volume
 - Through negotiations and coordination with relevant ministries and local governments, collection entities, etc., we have achieved a roughly threefold increase from 2023 in the number of contracts with cedar pollen collection entities in 2024
- ✓ Capital investment in drug substance manufacturing (approximately ¥3.0 billion, scheduled to be in operation in 2025)

Impact on financial performance

- ✓ Even amid continuing limited shipments of introduction doses, shipments of introduction and maintenance doses continue in line with our expectations, and we expect continued sales growth
 - Financial forecasts for FY2024 assume continued limited shipments of introduction doses
 - The guidance for FY2026 and VISION2030 targets are set under certain assumptions regarding the timeframe for limited shipments of introduction doses

With regards to the status of our efforts to ensure a stable supply and increased production of CEDARCURE, with the establishment of the Source Materials Procurement Department in August 2023, we have started the planning and execution of a new collection scheme aimed at dramatically increasing our cedar pollen collection volume.

We are also taking steps to increase production, including approximately 3 billion yen capital investment in drug substance manufacturing.

With regards to the impact of the limited shipments on our financial performance, as mentioned above, even amid continuing limited shipments of introduction doses, shipments of introduction and maintenance doses continue in line with our expectations, and we expect continued sales growth.

Our financial forecasts for FY2024 assume continued limited shipments of introduction doses. The guidance for FY2026 and the VISION2030 targets are also set under certain assumptions regarding the timeframe for limited shipments of introduction doses.

Outline of the Medium-Term Management Plan 2024-2026 –Major Initiatives–

- Enhance Corporate Governance

- Transition to a company with an Audit and Supervisory Committee to enhance and reinforce corporate governance
- Our new Board of Directors structure will enable diverse values to be reflected into management, thereby enhancement of corporate value
- Continue our efforts to ensure independence from controlling shareholders and protect minority shareholders

Transition to a company with an Audit and Supervisory Committee

- ✓ Strengthen the supervisory function of the Board of Directors by enabling Directors who are members of the Audit and Supervisory Committee to hold voting rights at meetings of the Board of Directors, and enabling the Audit and Supervisory Committee to appropriately exercise its right to state opinions on nomination and compensation
- ✓ The transition will enable the Board of Directors to delegate important decision-making regarding business execution to the executive Directors, which is to be coupled with the provision of consideration to the realization of further prompt decision-making in relation to management issues

New Board of Directors structure

- ✓ Total of five members of the Board (including one female), including two Representative Directors (President and Vice President) and three Independent Outside Directors (Audit and Supervisory Committee Members)
- ✓ Balanced composition of diverse members with extensive experience and expertise in corporate management/management strategy, legal affairs/compliance/risk management, finance/accounting, and capital markets

Ensure independence from controlling shareholders and protect minority shareholders

- ✓ Maintaining a system under which Independent Outside Directors constitute a majority of the Board of Directors
- ✓ Torii plans to establish the Nomination and Compensation Advisory Committee, which will be comprised only of Independent Outside Directors

Next, I will explain our efforts to enhance corporate governance.

As we announced in November last year, our company has resolved to transition to a company with an Audit and Supervisory Committee, subject to the approval of the General Meeting of Shareholders in March this year. In addition to strengthening the supervisory function of the Board of Directors, we are also working to enhance and strengthen our corporate governance by promoting consideration of the realization of further prompt decision-making in relation to management issues.

In addition, our new Board of Directors structure will enable diverse values to be reflected into management and thereby lead to the enhancement of corporate value. From the viewpoint of ensuring independence from controlling shareholders and protecting minority shareholders, we will continue to maintain a system under which Independent Outside Directors constitute a majority of the Board of Directors, and plan that the Nomination and Compensation Advisory Committee that will be newly established will be comprised only of Independent Outside Directors.

Outline of the Medium-Term Management Plan 2024-2026 –Major Initiatives–

- Initiatives on Sustainability

- Establishment and launch of the Sustainability Committee (FY2024)
- Upgrade the materiality implementation plan (setting goals, roadmap, KPIs, etc.)

Links between materiality and business strategies, major initiatives of the Medium-Term Management Plan, etc., and the overview of major promotion measures 1)

Materiality related to our business	Business strategies, major initiatives of the Medium-Term Management Plan, etc.	Overview of major promotion measures
1) Contribute to patients by providing high-quality and valuable medical information to medical professionals	Business strategy Create a framework for maximizing product value. Spread, cultivate, and maximize the value of new drugs in the growth phase.	<ul style="list-style-type: none"> • Strengthen our system and capability for providing and collecting information on our pharmaceutical products. • Utilization of digital technology.
2) Contribute to patients by exploring and developing new and valuable drugs that meet unmet medical needs.	Business strategy Enhance in-licensed activities.	<ul style="list-style-type: none"> • Initiatives to reinforce in-licensing activities (expansion of exploration areas, geographical expansion, expansion of exploration methods, increasing and enhancing personnel/reinforcing organizational capabilities, etc.) • Promote new drug development (JTE-061, TO-208, NAC-GED-0507, GRAZAX, etc.)
3) Co-create with diverse partners with specialized functions in order to maximize the value we deliver to the medical field.	VISION2030 (our business model). Focus on core functions × collaboration with companies specializing in each function.	<ul style="list-style-type: none"> • Continue and upgrade the initiatives described on the left in each division.
4) Supply our products stably through our entire supply chain initiatives.	Foundation for business operation Stable supply.	<ul style="list-style-type: none"> • Strengthen the CEDARCURE production system (establishment of the Source Materials Procurement Dept., construction of new drug substance manufacturing building, etc.) • Address development theme items (JTE-061, TO-208) • Appropriate supply and demand management.
5) Assure the quality and ensure the safety of our products.	Foundation for business operation Quality assurance.	<ul style="list-style-type: none"> • Respond to various revisions in pharmaceutical regulations. • Implementation based on schedule for developed drugs and in-licensed drugs.

Next, I would like to discuss our initiatives on sustainability.

Since identifying and announcing the key issues for our company as 11 materialities in the last fiscal year, we have worked to organize the links between the materialities, our business strategies, and major initiatives of the Medium-Term Management Plan in greater detail.

During this fiscal year, we plan to establish a Sustainability Committee. We will also work to upgrade the materiality implementation plan, including by setting the goals, roadmap and KPIs, etc.

Please refer to the table on the slide for the links between materiality and business strategies, major initiatives of the Medium-Term Management Plan, etc., and an overview of the major promotion measures.

The current slide shows the links with materiality related to our business.

Outline of the Medium-Term Management Plan 2024-2026 –Major Initiatives– - Initiatives on Sustainability

Links between materiality and business strategies, major initiatives of the Medium-Term Management Plan, etc., and the overview of major promotion measures 2)

Materiality related to our management foundation	Business strategies, major initiatives of the Medium-Term Management Plan, etc.	Overview of major promotion measures
6) Corporate activities with environmental protection in mind	Environmental response	<ul style="list-style-type: none"> Formulate and promote the environmental action plan (reduce greenhouse gas emissions and maintain waste recycling rate)
7) Develop employees with high levels of expertise and provide them with growth opportunities	Education and training/human resource development	<ul style="list-style-type: none"> Company-wide training, job-specific training Career development support Self-improvement support
8) Cultivate a corporate culture of implementing TORII's POLICY (Our Important Values)	Corporate culture reform	<ul style="list-style-type: none"> Understanding and dissemination of the corporate philosophy system (workshops for all employees, President dialogue sessions, public hearing from executives for employees) Conduct corporate culture reform questionnaires Conduct corporate culture reform working groups Improve human resource systems Initiatives to promote the active participation of women and support the development of the next generation Promote of health and productivity management
9) Realize an environment in which each and every employee works enthusiastically	Maintenance of human resource systems in line with management strategies and work-style reforms	<ul style="list-style-type: none"> Compliance with various laws and regulations (review of Code of Conduct, etc.) Compliance with industry rules (Code of Practice, fair competition code, guidelines on sales information provision activities, etc.) Provide education and awareness raising training to employees Conduct compliance questionnaires Establish a point of contact for reporting and consultation
10) Compliance	Foundation for business operation: Compliance	<ul style="list-style-type: none"> Decision to transition to a company with an Audit and Supervisory Committee Enhancement of information disclosure (financial results briefings, implementation of SR activities) Action to implement management that is conscious of cost of capital and stock price
11) Corporate governance	Enhance corporate governance	

Refer to this table for the links with materiality related to our management foundation.

AGENDA

- Progress in 2023 toward the Medium-Term Management Plan 2023-2025
- Medium-/Long-Term Business Vision "VISION2030"
- The Medium-Term Management Plan 2024-2026
- **Enhancement of corporate value**

Finally, I would like to explain our enhancement of corporate value.

This section explains our disclosure on December 28, 2023 of initiatives to enhance corporate value, including action to implement management that is conscious of the cost of capital and the stock price, including with some details that have been updated since that time.

Enhancement of Corporate Value: Current Status

- PBR has been less than 1.0x since 2019, and has also remained in the 0.8 to 0.9x range in 2023
- The background is attributed to a variety of factors: low ROE level, unclear growth strategy and corporate governance, etc.

PBR and ROE trends

- ✓ Over the past few years, PBR has trended below 1.0x and ROE at approx. 3.0%

[PBR*]

2018	1.07x
2019	0.76x
2020	0.94x
2021	0.81x
2022	0.81x
2023	0.93x

[ROE]

2018	1.3%
2019	27.3%
2020	3.1%
2021	2.9%
2022	3.3%
2023	3.4%

*PBR values are calculated using the highest stock price of each fiscal year

Analysis and evaluation

- ✓ The background of less than 1.0x PBR is the following:
 - Shareholders' equity increased significantly due to receipt of lump sum payment (approx. ¥40 billion) in 2019 following return of sales rights for anti-HIV drugs
 - ROE remaining at a low level (approx. 3.0%) due to an increase in shareholders' equity and a decrease in profits
 - Unclear growth strategy as well as lack of convincing explanation
 - Growth expectations for enhancing corporate value have not been raised
 - Further enhancement of corporate governance and the need for active communication with investors

First, the current status of our efforts for the enhancement of corporate value is as shown here. A description of the PBR and ROE for 2023 have been added from the details that were disclosed at the end of last year.

Enhancement of Corporate Value : Targets

- We have set the following targets for further enhancement of corporate value.

* For details of specific initiatives, please refer to [our website \(Initiatives for enhancement of Corporate Value \(available only in Japanese\)\)](#).

Achieve the numerical targets of "VISION2030"

("Net sales: Over JPY 80.0 BN" "Operating income: Operating income comes within the range of breaking the all-time high in 2032")

Achieve ROE of 8% or higher in 2030 or as soon as possible thereafter

(Specific ROE target and timing for achievement will be disclosed when a certain degree of progress in intensive business investment becomes foreseeable)

Achieve DOE level that compares favorably with that of other companies within the same industry (currently approx. 3.5%), while focusing on net sales and profit growth through business investment

(Specific timing for achievement will be disclosed will be disclosed when a certain degree of progress in intensive business investment becomes foreseeable)

Also, we have set the following as targets and will work to achieve them.

Achieve the numerical targets of "VISION2030"

Achieve ROE of 8% or higher in 2030 or as soon as possible thereafter

Achieve DOE level that compares favorably with that of other companies within the same industry (which is currently approximately 3.5%), while focusing on net sales and profit growth through business investment

For details of specific initiatives, please refer to [our website \(Initiatives for Enhancement of Corporate Value\)](#).

Enhancement of Corporate Value : Capital Allocation

- Prioritizing the use of funds in hand for business investment, with the aim of enhancing our mid to long-term corporate value through business investment, while also considering costs of capital

Image of capital allocation from 2023 to the end of 2027



Growth strategy

- ✓ Enhance mid to long-term corporate value through "maximizing the value of existing products and developed products" as well as "obtaining new in-licensed drugs." Assuming business investment of approx. ¥40 billion until the end of 2027. Executed and/or made decisions on the investments of over JPY 5.0 BN in FY2023 ※ [For information on the progress of investments in FY2023, see slide 21](#)
- ✓ Our basic approach to business investment will be to use funds in hand. If additional funds are needed, we will make aggressive investments, including considering borrowing and other financing
- ✓ It is difficult to indicate specific investment targets or plans. For investments that have been decided, we will disclose the amount and content as appropriate

Shareholder returns

- ✓ Our basic policy on shareholder returns is to distribute continuous and stable dividends. Our shareholder return indicator will be based on DOE for the time being. In the future, we will aim for a level that compares favorably with that of other companies within the same industry (currently approx. 3.5%). We will regularly evaluate the extent to which we have enhanced our development pipeline as well as our financial conditions. We will flexibly consider further enhancement of shareholder returns, such as raising the level of dividends.
- ✓ Regarding the repurchase of treasury stock, we will consider whether or not to implement and their scale, comprehensively taking into consideration the business environment and the progress of investments, etc.

Funds in hand at the end of 2027

- ✓ A certain amount of funds in hand will be necessary even at the end of 2027, taking into account the working capital required for business operations and investment capacity in 2028 onward

With regards to our thinking on capital allocation for the achievement of the targets, as shown in the slide, we are prioritizing the use of funds in hand for business investment, with the aim of enhancing our mid to long-term corporate value through business investment, while also considering the costs of capital.

In order to achieve the VISION2030 target and ensure sustainable growth thereafter, we will position the five years from 2023 to 2027 as a period for concentrated business investment, and as a guideline, we expect to utilize approximately 40 billion yen for business investment such as to obtain new in-licensed drugs and for development. In fiscal 2023, we executed and/or made decisions on investments of over 5 billion yen.

In addition, for shareholder returns, our basic policy is to distribute continuous and stable dividends while also taking into account the working capital required for normal business operations and our investment capacity from fiscal year 2027 onward, and keeping a certain amount of funds in hand. At the same time, while taking into account business performance and investment progress, we will strive to improve our medium- to long-term DOE, and aim to achieve a level that compares favorably with that of other companies within the same industry (which is currently approximately 3.5%).

Enhancement of Corporate Value : Shareholder Return Policy and Dividends

- The shareholder return policy is to distribute continuous and stable dividends as well as enhancing mid to long-term corporate value through business investment
- Our shareholder return indicator is DOE. The target is a level that compares favorably with that of other companies within the same industry (currently approx. 3.5%)
- Flexibly consider further enhancement of shareholder returns, such as raising the level of dividends through evaluating the development pipeline and financial conditions regularly

[Dividend per share trend (annual)]



2023 dividend

- ✓ Increased probability of future growth through favorable progress in promoting new drug development (filed application for approval of manufacturing and sales of JTE-061, favorable top-line results of TO-208 Phase III clinical study), acquisition of two new in-licensed drugs (NAC-GED-0507, GRAZAX), etc.
- ✓ Based on the above results and mid to long-term financial forecasts, etc., increased dividends from the latest annual dividend forecast of ¥100 per share to ¥120, in accordance with the concept of enhancing shareholder returns (Interim dividend: ¥50, year-end dividend: ¥70)

2024 dividend

- ✓ In accordance with the basic policy and concept above, we plan to pay a dividend of ¥120 per share (Interim dividend: ¥60, year-end dividend: ¥60)

With regards to the 2023 dividend, we plan to increase dividends from the latest annual dividend forecast of 100 yen per share to 120 yen per share. This is because the probability of future growth has increased, such as due to our favorable progress in promoting new drug development and our acquisition of two new in-licensed drugs (NAC-GED-0507 and GRAZAX), and based on mid to long-term financial forecasts, etc., and is in accordance with the concept of enhancing shareholder returns. We also plan to continue the dividend of 120 yen per share in 2024.

This concludes the explanation.



TORII PHARMACEUTICAL CO., LTD.

Important notes on forward-looking statements

The forecasts presented in this material are forward-looking statements. Reflecting assumptions based on information available on the date of publication, these statements are subject to inherent risks and uncertainties. Accordingly, unforeseen factors may cause actual results to differ materially from the projections contained herein. Torii will not necessarily revise this material regardless of any new information, future events or other results.

Minutes of Q&A Session at Financial Results Briefing for Fiscal Year Ended December 31, 2023

Date and Time: February 14, 2024 11:00 AM–12:00 Noon

Attendees:

- ✓ **Goichi Matsuda, Representative Director, President and Chief Executive Officer**
- ✓ **Nobumasa Kondo, Senior Executive Office, Head of Planning & Administration Group**

Question 1

Regarding the supply system of CEDARCURE, please provide an updated perspective on the expected pace of supply increase, based on insights gained from efforts made in 2023.

The reason for this question is that, while you have announced a policy to increase production in response to factors such as last year's surge in demand and the government's request, there has been considerable uncertainty about the extent of the necessary increase in supply capacity, depending on pollen collection and demand forecasting.

Answer 1 (Matsuda)

First of all, I would like to extend my apologies once again for the ongoing limited shipments of introduction doses of CEDARCURE.

Since last year, we have been expanding our manufacturing equipment and enhancing our systems to ensure pollen collection. Given that pollen is a natural substance, it is difficult to provide an accurate estimate of how much pollen can be collected.

Currently, we have no choice but to continue limited shipments throughout 2024, with the cessation of these limited shipments set for 2025 and onward.

Question 2

How is the supply system of CEDARCURE envisioned in this guidance? Also, if new manufacturing equipment for the drug substance begins operating in 2025, will you delay ceasing limited shipments until 2026 or later, instead of 2025?

Answer 2 (Matsuda)

It is true that certain assumptions have been made in the forecasts under "VISION 2030," but I would rather refrain from presenting specific details at this time.

To prevent any potential confusion among medical professionals, I am unable to disclose the assumptions we made. I intend to share them once a more accurate forecast is available. I would appreciate your understanding.

Question 3

Firstly, please provide us with background information on the rising cost of sales.

Secondly, it was explained that the increase in actual R&D expenses in 2023 was due to a one-time payment of ¥1.6 billion. Do you anticipate incurring a similar scale of R&D expenses in the financial forecasts for 2024?

Additionally, what accounts for the double-digit increase in CEDARCURE sales in the 2024 financial forecasts, despite the ongoing limited shipments?

Answer 3 (Kondo)

Firstly, cost of sales are being affected by recent price hikes, as well as increases in labor and energy costs. In fact, our contract manufacturers have requested a price increase from us. I expect this situation to continue for the time being. Moreover, the frequent importation of products from overseas has a negative impact on the costs due to fluctuations in foreign exchange rates. Given the expected persistence of the negative foreign exchange impact, we have incorporated it into our financial forecasts.

Secondly, we recorded a one-time payment of approximately ¥1.6 billion for in-licensed drugs from Nogra Pharma Ltd. as R&D expenses in 2023. In 2024, despite a drop-off of this one-time payment, a certain amount of R&D expenses associated with the developed products that were in-licensed in 2023 will be incurred. As a result, R&D expenses in 2024 are expected to remain at almost the same level as the previous year.

Additionally, limited shipments of CEDARCURE do not imply our inability to ship at all; rather, they represent our inability to meet market demand with the required quantity. While limited shipments are intended for treatments for new patients (introduction dose), the number of shipments will increase to accommodate a certain number of additional new patients.

Question 4

Cost of sales in FY2023 increased by approximately ¥4.3 billion year on year. Please explain the factors contributing to this increase.

Answer 4 (Kondo)

Firstly, as sales volume increases, costs rise proportionally. Another factor contributing to the increase is the escalation in purchasing unit prices, alongside the negative foreign exchange impact. Regarding the impact of foreign exchange, it is currently unlikely that the yen will weaken further in the future. As this is beyond our control, providing a precise forecast is difficult.

Question 5

Please share the development pipeline forecasts for 2024.

Answer 5 (Matsuda)

JTE-061 is expected to be approved for two indications of atopic dermatitis and psoriasis vulgaris by the end of 2024, with its subsequent market launch contingent upon progress as planned. We will also continue the development for pediatric atopic dermatitis.

As for TO-208, we achieved favorable results in the Phase III clinical study in 2023. If everything proceeds smoothly, I believe there is a reasonable chance that the application will be filed by the end of 2024. Also, research and development of TO-208 for another disease indication is currently in progress, and the associated R&D expenses will be recorded in 2024.

Regarding the developed products that were in-licensed in 2023, I am unable to provide detailed information on their future development outlook. I would appreciate your understanding.

Question 6

It was presented that a specific ROE target and timing for achievement “would be disclosed when a certain degree of progress in intensive business investment becomes foreseeable.” When exactly are they expected to be disclosed?

The reason for this question is because I believe it is essential to clarify this point when considering the corporate value of your company. I would appreciate your opinion on this.

Answer 6 (Matsuda)

Given the planned period of intensive business investment leading up to 2027, I anticipate being able to make a certain forecast shortly before that year. However, the business investment is primarily made for in-licensing, and consequently, I am unable to provide specifics such as the timing of the in-licensing and respective estimated investment amounts at this time.

As for the forecast, we will determine prospective investment results based on “whether we have firmly attained VISION 2030” and “whether we have established a foundation for achieving sustainable growth beyond 2030.”

Question 7

Am I correct in understanding that further new in-licensed drugs are required, in addition to the current pipeline, to realize VISION 2030?

Answer 7 (Matsuda)

I acknowledge that the accuracy of realizing VISION 2030 has improved to a certain extent. I believe that new in-licensed drugs will be obtained during the period of intensive business investment, primarily in terms of achieving sustainable growth beyond 2030.

Question 8

In light of the government's request for increased production, how are you coordinating with the administration and the Ministry of Health, Labour and Welfare to ensure a stable supply of CEDARCURE? Is the pollen collection proceeding smoothly for a stable supply of CEDARCURE?

Answer 8 (Matsuda)

Coordinating our initiatives, we have established a cooperative framework with the administration for cedar pollen collection. Collecting cedar pollen requires cooperation from various entities, including forest associations. Collaboration with the administration has greatly increased the number of entities cooperating in cedar pollen collection. However, it takes some time for newly engaged entities to become proficient in collecting pollen. Therefore, going forward, we will strive to establish enhanced cooperative relationships with the entities to support them in achieving smooth pollen collection.