

Message from the President



We operate our business from day to day in line with Torii Pharmaceutical's Purpose: a commitment to "sincerely serving patients, their families, and those involved in medical care" and to "contributing to the healthy recovery of patients, as well as to a happy, enriched life free from fear of illness." Moreover, in achieving this, we "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."

As we strive to fulfill Torii Pharmaceutical's Purpose, we will continue to take on the challenge of contributing to healthcare that only we can make. We would like to express our sincere thanks to everyone for their continued support and understanding.

Goichi Matsuda

Representative Director,
President and Chief Executive Officer

Review of Operations in Fiscal 2022

The business environment surrounding the pharmaceutical industry was extremely challenging, owing mainly to soaring prices of raw materials and other resources, inflation resulting from the sharp depreciation of the yen, annual NHI drug price revisions. Furthermore, business activities were affected to a certain extent by factors associated with the prolonged COVID-19 pandemic, such as the tendency of patients to refrain from visiting medical institutions and self-imposed restrictions on visits to medical institutions by medical representatives (MRs).

In these circumstances, in order to realize its Medium-/Long-Term Business Vision "VISION2030" toward fiscal 2030, Torii launched the Medium-Term Management Plan 2022-2024 and is pursuing initiatives based on the growth strategy. As a result, for fiscal 2022, we achieved net sales of ¥48,896 million (up 4.1% year on year, including the impact of the application of the Accounting Standard for Revenue Recognition), operating income of ¥5,540 million (up 19.0% year on year), ordinary income of ¥5,537 million (up 14.2% year on year), and net income of ¥3,944 million (up 16.9% year on year), and we made a good start for the first year of the Medium-Term Management Plan 2022-2024.

Net sales in fiscal 2022 were driven by increased sales volumes in the allergens area and the skin disease area. In

the allergens area, sales volumes of CEDARCURE and MITICURE increased due to further spread of allergen immunotherapy. In the skin disease area, along with greater market penetration of CORECTIM, its sales volume increased, including formulations with additional pediatric indication.

In terms of profit, although cost of sales increased owing to foreign exchange fluctuations, and sales-linked expenses and clinical trial expenses increased, these increases were offset by an increase in net sales.

Progress of Medium-Term Management Plan and Future Development

The numerical indicators of VISION2030 announced in February 2022 are net sales breaking the all-time high (¥64.1 billion for fiscal 2017) and operating income coming within the range of breaking the all-time high (¥13.3 billion for fiscal 2001) in fiscal 2030. To achieve these targets, we are implementing a business strategy focusing on reinforcement of in-licensing activities and creation of a framework for maximizing product value. We intend to generate good results through the Medium-Term Management Plan. The Medium-Term Management Plan is on a rolling basis and we will review the plan for the next three years annually based on changes in the market environment to respond quickly and flexibly to changes in the market environment.

In the first year of the Medium-Term Management Plan 2022-2024, the initiative to spread, cultivate, and maximize the value of new drugs in the growth phase, namely, ENAROY, Riona, CORECTIM, CEDARCURE, MITICURE, and ORLADEYO, led to increases in the sales volume of each of these products, resulting in the gratifying financial results mentioned above. We will continue to focus on expanding indications and adding new dosage and administration to spread, cultivate, and maximize the value of new drugs in the growth phase.

In new drug development, we are making good progress for drugs in the pipeline. We are conducting Phase III clinical study of JTE-061 in Japan, a topical skin disease treatment drug, for the indications of atopic dermatitis and psoriasis vulgaris, and have obtained the top-line results of the Phase III clinical study in Japan for each indication. We began Phase III clinical study of TO-208 in Japan, another skin disease treatment drug for indications of molluscum contagiosum.

As for in-licensing activities, our negotiations with Nogra Pharma Limited, an Irish company, bore fruit and Torii entered into a license agreement with Nogra Pharma Limited on January 26, 2023 with respect to the exclusive development and commercialization of Nogra's skin disease treatment drug NAC-GED-0507 in Japan.

In fiscal 2023, Torii has formulated the Medium-Term Management Plan 2023-2025 that covers the period from fiscal 2023 to fiscal 2025. As we made good progress in major initiatives and financial results in fiscal 2022, we will not make any major strategy changes, and will continue with the two pillars of "growth strategy" and "maintaining the trust of stakeholders."

Net sales for fiscal 2023 are expected to increase compared to the previous fiscal year owing to an increase in sales volumes of CEDARCURE and MITICURE in the allergens area as allergen immunotherapy becomes more widespread, and an increase in sales volume of CORECTIM in the skin disease area, including pediatric indications. On the other

hand, with respect to profit, R&D expenses are expected to increase because of an upfront licensing fee associated with the in-licensing of the above-mentioned NAC-GED-0507. Based on the above assumptions, we forecast an increase in net sales and decreases in profits for fiscal 2023, with net sales of ¥50.9 billion (up 4.1% from fiscal 2022), operating income of ¥4.1 billion (down 26.0%), ordinary income of ¥4.4 billion (down 20.5%), and net income of ¥3.1 billion (down 21.4%). However, since our financial results fluctuate greatly due to the recording of R&D expenses, in the Medium-Term Management Plan we use operating income before deduction of R&D expenses as an indicator of profit growth. Operating income before deduction of R&D expenses in the fiscal 2023 forecast is expected to be ¥7,630 million (up 6.0%), maintaining the profit growth trend.

Financially, the next five years through fiscal 2027 are positioned as a period of intensive business investment, with a rough estimate of ¥40.0 billion to be used for in-licensing and other purposes. Centering on in-licensing, we also envisage investment in equipment and systems. We will work to implement the Medium-Term Management Plan thoroughly to establish the foundation for sustainable growth and enhancement of corporate value while continuing to contribute to healthcare.

Basic Policy on Sustainability and Materiality

Torii established the Basic Policy on Sustainability in February 2023 and identified material issues (materiality) to be addressed based on this policy. In view of the Basic Policy on Sustainability and the identified materiality, we added "initiatives on sustainability" as a measure for maintaining the trust of shareholders in the Medium-Term Management Plan 2023-2025 that I explained earlier.

To date, based on the 4S MODEL, we have been striving to fulfill our responsibilities to our customers, shareholders, society, and employees in a balanced way and enhance their overall satisfaction through the circulation/expansion of capital generated by our high-quality business activities. The Basic Policy on Sustainability is reorganization of the 4S MODEL from the perspective of contributing to a sustainable society, and shows our commitment to realizing our corporate philosophy, Torii Pharmaceutical's Purpose.

The material issues identified are classified into materiality related to our business and materiality related to our management foundation. Materiality related to our business includes themes such as exploration and development of new drugs, provision of medical information, quality and safety, stable supply, and co-



Message from the President

creation with diverse partners. Materiality related to our management foundation includes themes such as human resources development, corporate culture, working environment, corporate governance, compliance, and environmental protection.

Going forward, we will continue to work to promote sustainability based on the 4S MODEL, and we will enhance the initiatives we carry out based on our Basic Policy on Sustainability and materiality. We plan to disclose details regarding these initiatives and related information through our website, etc.

To Our Stakeholders

Placing an emphasis on distributing dividends in a continuous and stable manner, we have continued to pay annual dividends of ¥48 per share (interim dividend of ¥24 and year-end dividend of ¥24) since fiscal 2015. In view of our investment and financial status from a medium- to long-term perspective focused on business growth, we have decided to enhance our shareholder returns. Accordingly, we increased the year-end dividend from the initial plan of ¥24 per share to ¥76 per share. Together with the interim dividend of ¥24 per share, the annual dividend amounted to

¥100 per share. For fiscal 2023, we also plan to pay an annual dividend of ¥100 per share, consisting of an interim dividend of ¥50 and a year-end dividend of ¥50. We will maintain our basic policy of continuous and stable dividends while further enhancing our shareholder returns. In order to meet our shareholders' expectations, while working to further improve our financial performance, we will strive to improve the dividend on equity ratio (DOE) over the medium to long term, aiming for a DOE level that compares favorably with that of other companies within the same industry.

In recent years, we have been promoting business structure reform to respond to changes in the external environment and our earnings base, and have established a foothold for renewed growth. As a result, we are poised for the next leap forward, securing new growth potential and strengthening profitability through steady progress with our R&D pipeline, maximizing product value, and acquiring new in-licensing opportunities.

In closing, I would like to reiterate that, to realize our corporate philosophy, Torii Pharmaceutical's Purpose, with the aim of surely attaining VISION2030, we are committed to definitely achieving the results that will lead to sustainable growth. We look forward to your continued support in our endeavors to develop the business from now on.

Principal Products in the Research and Development Pipeline (As of February 10, 2023)

Development code [Product name]	Indication	Formulation/ Route of administration	Development stage (domestic)					Remarks
			Phase I	Phase II	Phase III	Application	Approval	
Skin diseases								
JTE-061	Atopic dermatitis	Topical			Phase III			<ul style="list-style-type: none">● Compounds for which JT has entered into a license agreement with Dermavant Sciences GmbH for an exclusive license to develop and commercialize skin diseases in Japan● License agreement signed with JT for development and commercialization
	Psoriasis Vulgaris	Topical			Phase III			<ul style="list-style-type: none">● Compounds for which JT has entered into a license agreement with Dermavant Sciences GmbH for exclusive development and commercialization in the skin disease area in Japan● License agreement signed with JT for development and commercialization
	Atopic dermatitis in children	Topical		Phase II				<ul style="list-style-type: none">● Compounds for which JT has entered into a license agreement with Dermavant Sciences GmbH for exclusive development and commercialization in the skin disease area in Japan● License agreement signed with JT for development and commercialization
TO-208	Molluscum contagiosum	Topical			Phase III			<ul style="list-style-type: none">● License agreement signed with Verrica Pharmaceuticals Inc. for exclusive development and commercialization in Japan● In-house● Verrica Pharmaceuticals Inc. the development code: VP-102
Allergens								
TO-203 [MITICURE® House Dust Mite Sublingual Tablets]	House dust mite induced allergic asthma (Allergen immunotherapy)	Sublingual tablet		Phase II/III (Study completed)*				<ul style="list-style-type: none">● License agreement signed with ALK for providing exclusive development and sales rights in Japan● In-house*Examining the future development policy

Update since the previous announcement of financial results and reference materials on October 31, 2022

- In January 2023, revised the package insert based on the results of Phase III clinical study of JTE-052 [CORRECTIM® Ointment] (atopic dermatitis in infant) by JT. (Previous announcement: Development stage Phase III)

Additional Information

- In January 2023, Torii entered into a license agreement with Nogra Pharma Limited (Nogra) with respect to the exclusive development and commercialization of Nogra's skin disease treatment drug NAC-GED-0507 for the treatment of acne in Japan.

Torii and its parent company JT (specifically, the pharmaceutical division of JT) each leverage their own pharmaceutical product and service strengths. Torii is primarily responsible for manufacturing and marketing functions, while the parent company is responsible for research and development functions. For JT's clinical research and development, please refer to the following posted on JT's website:

https://www.jt.com/investors/results/S_information/pharmaceuticals/index.html