## Annual Report 2021

For the year ended December 31, 2021

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## Corporate Philosophy

## 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.

## Corporate Philosophy System

Corporate Philosophy

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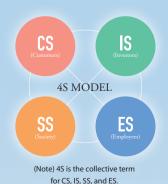
Our Important Values

## **TORII's POLICY**

- Treasure all human connections
- Sincerity and commitment are Torii's finest qualities
- We all have a stake. We all have a role
- Try new things without fear
- All of our past experiences fuel our continued growth

Basic Management Stance

**4S MODEL** 



Through the circulation/expansion of capital generated by our high-quality business activities, we will fulfill our responsibilities to our customers, shareholders, society, and employees in a balanced way and enhance their overall satisfaction.

(Customer Satisfaction): Our Responsibility to Customers

We strive to improve the quality of life (QOL) of patients by supplying superior medicines and accurate information through medical professionals.

(Investor Satisfaction): Our Responsibility to Shareholders

We disclose timely, accurate corporate information and endeavor to generate appropriate shareholder returns and improve our corporate value.

(Social Satisfaction):

We maintain a high ethical standard regarding our corporate social responsibility through business activities that reflect

Our Responsibility to Employees (Employee Satisfaction):

We aim to provide motivation and fulfillment to all our employees by respecting every individual, ensuring equal opportunities for career advancement, and by treating employees fairly on the basis of unbiased assessments.

## 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 the Previous Medium-Term **Management Plan**

The Medium-Term Management Plan 2021 was completed in fiscal 2021. While the business environment for the pharmaceutical industry became increasingly challenging owing to the drastic reform of the NHI drug pricing system and other developments, the emergence of generic products following the expiration of the patent for REMITCH, one of our mainstay products, and termination of the licensing agreements for six anti-HIV drugs had a significant financial impact on Torii. We launched the Medium-Term Management Plan 2021 in fiscal 2019 in order to promote transformation of Torii to overcome such adversity.

The initial target of the Medium-Term Management Plan 2021 was to turn operating income (excluding expenses relating to new business investments) positive in fiscal 2022, after the completion of the plan, as we assumed that the Company would remain unprofitable during the three-year period covered by the plan. However, we achieved this target in fiscal 2019, the first year of the plan. So, we revised the targets of the plan to keep operating income (excluding expenses relating to new business investments) positive and to increase profit throughout the period covered by the plan. Although operating income in fiscal 2021 decreased somewhat from the previous fiscal year, we achieved profitable

operation for the three years and net sales, which had been decreasing, increased in fiscal 2021.

Under the Medium-Term Management Plan 2021, we implemented three key measures: business structure reform, growth strategy, and maintaining the trust of stakeholders. With regard to business structure reform, in response to the situation in which we lost a large portion of the previous earnings base, we made tough decisions and carried out initiatives in order to improve the profit structure through fixed cost reduction, including consolidation and elimination of branches, integration of R&D functions into Japan Tabacco Inc. (JT), transfer of the Sakura Plant, and implementation of a special program supporting employees' career changes. In terms of the growth strategy, we expanded our product lineups and added new lines from 2020 onward, including launches of ENAROY Tablets, CORECTIM Ointment, and ORLADEYO Capsules as well as additional indication for Riona Tablets. As for in-licensing, we entered into new licensing agreements for three products, including the above-mentioned ORLADEYO Capsules, during the period covered by the plan.

Regarding maintaining the trust of stakeholders, in March 2020, Torii received a cease and desist order and a surcharge payment order from the Japan Fair Trade Commission (JFTC) pursuant to the Antimonopoly Act for a violation of the

Antimonopoly Act concerning the setting of the wholesale price of the CALVAN Tablets. Taking these orders gravely and seriously, we have implemented measures to prevent recurrence of the violation of the Antimonopoly Act and taken all possible steps to comply with various regulations. We have put in place a system to ensure thorough compliance and enhanced corporate governance.

Despite restrictions on sales activities due to the impact of COVID-19 from fiscal 2020 onward, we responded to the situation by making effective use of IT and maintained profit throughout the period covered by the Medium-Term Management Plan 2021 and achieved steady results with the three key measures. Thus, I think we were able to reinforce the foundation, which was the goal of the previous plan. As the head of Torii, I would like to express my deepest appreciation to our stakeholders for their understanding and support while I strengthen my resolve to make further strides toward Torii's sustainable growth.

## **Background to Formulation of** the New Corporate Philosophy and Aspirations

Torii formulated its new corporate philosophy called Torii Pharmaceutical's Purpose and announced its corporate philosophy system based on the purpose and consisting of TORII's POLICY (Our Important Values) and the 4S MODEL (Basic Management Stance).

While change continues in the external environment surrounding the pharmaceutical industry, our internal environment has also changed as a result of the business structure reform. In light of these environmental changes, Torii, once again, recognized the need to clarify the significance of its existence and its unchanging aspirations for the future. This was the background to formulation of the new corporate philosophy.

Torii celebrated the 100th anniversary of its establishment in 2021, which is followed in 2022 by the 150th anniversary of our founding. While retaining its corporate culture and the trust of stakeholders earned over its long history, Torii has defined its unchanging aspirations for the future as "Torii Pharmaceutical's Purpose" and made it Torii's new corporate philosophy.

TORII's POLICY was established through repeated discussion involving employees as part of the reform of the corporate culture we have been promoting in recent years. The policy defines the values we should share and is incorporated in the corporate philosophy system. On the other hand, the 4S MODEL has been an element of The Corporate Mission of Torii. Positioning the 4S

MODEL as Torii's basic management stance, we are committed to fulfilling our responsibilities to our customers, shareholders, society, and employees in a balanced way and enhancing their overall satisfaction.

#### VISION2030 and New Medium-Term **Management Plan**

Coinciding with the formulation of the new corporate philosophy, we formulated the Medium-/Long-Term Business Vision toward 2030, "VISION2030" to indicate what Torii is aiming for in the medium- to long-term. Although it is difficult to accurately forecast the change in the market and society nine years ahead and envisage the prospects of our business, we clarified our vision, taking into account the possible prospects available at this point in time.

Through VISION2030, we aim to achieve stable growth by overcoming fluctuations. What Torii aims for in 2030 is to be a pharmaceutical company with presence. The numerical targets for fiscal 2030 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).

For achievement of VISION2030, decisive action is required. Torii will work more aggressively than before on business investments for in-licensed drugs and will develop internal systems and improve the capabilities to accurately communicate the value of its products to medical professionals and patients. To this end, as key initiatives of our business strategy, we will work to enhance in-licensed activities and create a framework for maximizing product value.



Positioning the first three years as the first stage for realization of VISION2030, we formulated and launched the Medium-Term Management Plan 2022-2024. Under this new three-year management plan, our policy is to enhance the development pipeline by executing aggressive investments centering on acquisition of in-licensed drugs, while seeking to increase earnings by means of new drugs in the growth phase. For maximization of product value, while complying with the guidelines on sales information provision activities for drugs, we will implement an effective approach, such as introduction of digital tools and other new methods.

Starting with the Medium-Term Management Plan 2022-2024, Torii will formulate its medium-term management plan on a rolling basis. Therefore, instead of setting numerical targets for three years ahead, we present guidance in the form of rough estimates at a point in time, as reference values for three years ahead. Currently, we estimate new sales for fiscal 2024 in the range from ¥52.0 billion to ¥55.0 billion and operating income before deduction of research and development expenses in the range from ¥8.0 billion to ¥9.0 billion. In the current fiscal year, we are making good progress by implementing key measures of the Medium-Term Management Plan 2022-2024.

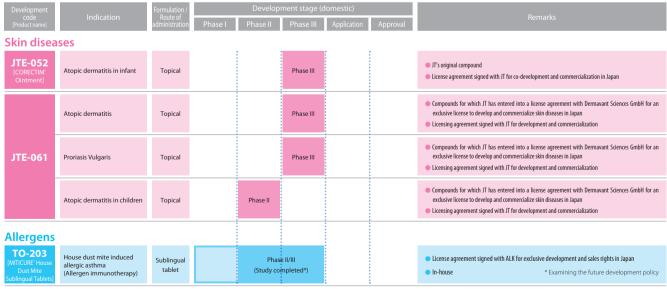
#### To Our Stakeholders

The business environment surrounding the pharmaceutical industry is rapidly changing. In order for Torii to continue to fulfill its responsibility to stakeholders, it is becoming increasingly necessary to continue to create new drugs that meet medical needs. In particular, during the period of the Medium-Term Management Plan 2022-2024, Torii will be more aggressive than before in making business investments centering on acquisition of inlicensed drugs. Taking this into account, regarding shareholder returns for fiscal 2022, Torii intends to maintain the current level of annual dividends of ¥48 per share.

In April 2022, Torii moved to the Prime Market in accordance with the Tokyo Stock Exchange market restructuring. In recent years, we have been reinforcing corporate governance, including response to the revision of the Corporate Governance Code. Going forward, we will step up our efforts to further enhance corporate governance, including strengthening of responses to sustainability issues and of information disclosure in view of the compliance with the governance standard required by the Tokyo Stock Exchange.

As stated in the 4S MODEL, we will fulfill our responsibilities to our stakeholders in a balanced way and enhance their overall satisfaction. 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, 2022)



#### Additional Information

• In March 2021, Torii has entered into a license agreement with Verrica Pharmaceuticals Inc. for an exclusive license to develop and commercialize VP-102 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 R&D functions.

For JT's clinical development of pharmaceuticals, please refer to the following posted on JT's website:

https://www.it.com/investors/results/S information/pharmaceuticals/

## Review of the "Medium-Term Management Plan 2021"

#### Overview of the Medium-Term Management Plan 2021

Initial target: to turn operating income\* positive in FY2022

Achieved profitability in FY2019, earlier than planned, reviewed the target



To keep operating income\* positive and to increase profit throughout the period covered by the Medium-Term Management Plan 2021

#### Business structure reform

- Optimization of the organizational structure, functions, and workforce
- Review of resource allocation and maximization of performance

#### Growth strategy

- Maximization of the value of products currently under co-development with JT
- Co-development of new innovative drugs with JT and acquisition of new in-licensed drugs
- Reinforcement of organizations and functions

#### Maintaining the trust of stakeholders

- Continuing initiatives for enhancing and reinforcing corporate governance and promoting compliance
- Responding to the changing needs of society

- Optimization of the organizational structure, functions, and workforce
- Review of resource allocation and maximization of performance
- Implementation of a special program supporting employees' career changes (supporting employees who wish to retire voluntarily and embark on a new career) (FY2019)
- · Reorganization (consolidation and elimination of branches, integration of R&D functions into JT, and reorganization of the head office) (FY2019)
- Transfer of production of long-term listed drugs to other companies (FUTHAN: FY2019, URINORM: FY2020)
- Introduction of a new sales support system and tablet terminals (FY2019)
- Transfer of the Sakura Plant to IWAKI SEIYAKU CO., LTD. (FY2020)

#### Results of major initiatives 2 Growth strategy

- Maximization of the value of products currently under co-development with JT
- Co-development of new innovative drugs with JT and acquisition of new in-licensed drugs
- Reinforcement of organizations and functions

#### Renal diseases and hemodialysis

- Torii and ASKA Pharmaceutical Co., Ltd. entered into a co-promotion agreement covering the additional indication of iron deficiency anemia for Riona Tablets (June 2020).
- $\bullet\;$  Launched ENAROY Tablets (2mg, 4mg), a drug for the treatment of anemia associated with chronic kidney disease (December 2020)
- · Received approval for an additional indication of iron deficiency anemia for Riona Tablets and started promotion (March 2021)

#### Skin dis

- Signed a license agreement with JT for co-development and commercialization of tapinarof (ITE-061) in Japan (January 2020), and started the Phase III clinical study for indications of atopic dermatitis and psoriasis vulgaris in Japan (October 2021)
- Launched CORECTIM Ointment 0.5% for the treatment of atopic dermatitis (June 2020)
- Received approval for CORECTIM Ointment 0.5% for an additional indication of pediatric atopic dermatitis (March 2021), and launched CORECTIM Ointment 0.25% (June 2021)
- · Entered into a license agreement with U.S. Verrica Pharmaceuticals Inc. for exclusive development and commercialization of Verrica's skin disease treatment drug VP-102 in Japan (March 2021)

- · Invested in a newly established fund in the life science field (July 2020)
- Launched ORLADEYO Capsules for the suppression of the onset of attacks in hereditary angioedema (HAE) (April 2021)

Results of major initiatives 3 Maintaining the trust of stakeholders

- Initiatives for enhancing and reinforcing corporate governance and compliance and for responding to various regulations
- Establishment of the Group for Supervision of Sales Information Provision and the Screening and Supervisory Committee based on the guidelines on sales information provision activities, introduction of document screening systems (FY2019)
- Response to the revision of the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (FY2020 and FY2021)
- · Revision of the management system to further separate management supervision from business
- →Independent Outside Directors constitute a majority of the Board of Directors.
- →Each Head of Group is assigned the role of executive officer and is responsible for the execution of business operations.
- · Application for listing on the Prime Market in accordance with the TSE market restructuring and response to the revision of the Corporate Governance Code (FY 2021)

#### Response to the violation of the Antimonopoly Act

In March 2020, Torii received a cease and desist order and a surcharge payment order from the Japan Fair Trade Commission (JFTC) pursuant to the Antimonopoly Act for a violation of the Antimonopoly Act concerning the setting of the wholesale price of the CALVAN Tablets. Taking these orders gravely and seriously, we are implementing measures to prevent recurrence. We will continue our efforts to ensure thorough compliance with laws and regulations in order to prevent recurrence and restore trust as soon as possible.

#### Management target achievement level

• Management target (after revisions made on February 6, 2020):

To keep operating income\* positive and to increase profit throughout the period covered by the Medium-Term Management Plan 2021

	Results for FY2019	Results for FY2020	Results for FY2021
Net sales	¥42.9 billion	¥41.7 billion	¥46.9 billion
Operating income	¥1.4 billion	¥4.7 billion	¥4.6 billion

\* Operating income excluding expenses relating to new business investments (investments including those for acquiring new in-licensed drugs and M&A)

#### Surplus dividends for FY2021

· In accordance with the basic policy of distributing dividends in a continuous and stable manner, Torii continued to pay an annual dividend of ¥48 per share in FY2021, the final year of the Medium-Term Management Plan 2021, while considering business investments for future growth.

<sup>\*</sup>Operating income excluding expenses relating to new business investments (investments including those for acquiring new in-licensed drugs and M&A)

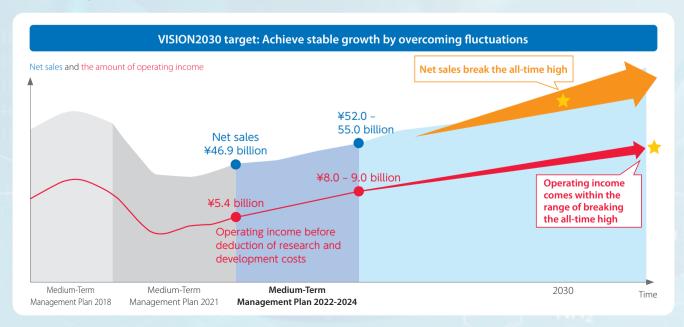
# Medium-/Long-Term Business Vision "VISION 2030"

Torii has formulated Medium-/Long-Term Business Vision "VISION2030" as what it is aiming for toward 2030 in order to achieve "Torii Pharmaceutical's Purpose," its new corporate philosophy and has also formulated the Medium-Term Management Plan 2022-2024 that covers the period from FY2022 to FY2024 to achieve VISION2030. Torii will continue to implement measures for its growth strategy and measures to maintain the trust of stakeholders in order to realize its Medium-/Long-Term Business Vision.

#### Medium-/Long-Term Business Vision "VISION2030"

To be a pharmaceutical company with presence: A company that has a deep understanding of the medical needs, What Torii aims for in 2030 leverages our expertise and impetus to co-create optimal solutions with all stakeholders, and delivers new, valuable pharmaceutical products to meet those needs. Net sales break the all-time high\*1 **Target of VISION2030** • Operating income comes within the range of breaking the all-time high\*2 \*1: ¥64.1 billion (fiscal year ended December 31, 2017) \*2: ¥13.3 billion (fiscal year ended March 31, 2001) **Business Strategy** Enhance in-licensed activities 2 Create a framework for maximizing product value

#### Medium-/Long-Term Business Vision "VISION2030"



# and Medium-Term Management Plan 2022-2024

#### Medium-Term Management Plan 2022-2024

#### Major initiatives of the Medium-Term Management Plan 2022-2024

#### **Growth strategy**

- Spread, cultivate, and maximize the value of new drugs in the growth phase (ENAROY, Riona, CORECTIM, CEDARCURE, MITICURE, ORLADEYO)
- Promote new drug development (JTE-061, VP-102)
- ▶ Reinforce in-licensing systems
- Maintenance of human resource systems in line with management strategies and work-style reforms
- Corporate culture reform

#### Maintaining the trust of stakeholders

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

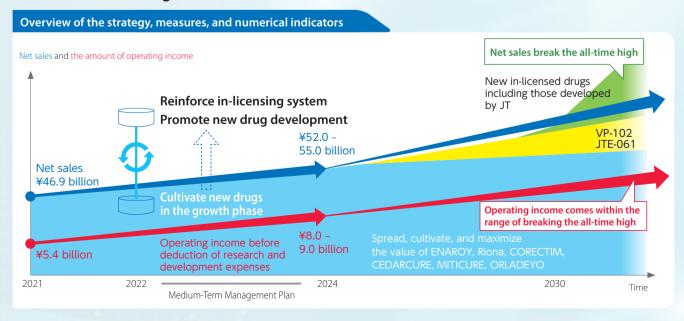
#### Numerical indicators for the Medium-Term Management Plan 2022-2024

Torii sets net sales and operating income before deduction of research and development expenses as numerical indicators for the Medium-Term Management Plan 2022-2024, in order to realize what VISION2030 aims for.



- \*1: It is difficult to foresee research and development expenses at this point in time, as these costs fluctuate significantly due to aggressive business investments for medium-/long-term growth. For this reason, Torii sets operating income before deduction of research and development costs as a numerical income indicator.
- \*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: ¥64.1 billion (fiscal year ended December 31, 2017)
- \*4: Operating income: ¥13.3 billion (fiscal year ended March 31, 2001)

## Medium-Term Management Plan 2022-2024 and VISION2030



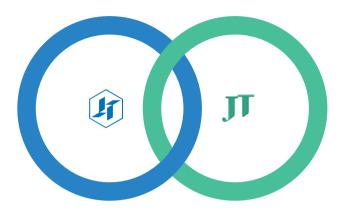
## Summary of Business

## Collaboration with Japan Tobacco Inc. (JT)

In the pharmaceutical industry, the technology required to develop new drugs is becoming increasingly sophisticated, and R&D costs are generally rising. At the same time, the requirements for new drug approval are becoming ever more demanding. As a result, it often takes many years to release a new product to market. In keeping with our tradition of always seeking and maximizing synergies, built over a corporate history dating back more than 130 years, Torii joined the JT Group in 1998. In 1999, we established a business collaboration with JT, which envisioned R&D oriented pharmaceutical activities. In this new partnership, R&D for new drugs came under the control of JT, while Torii took over sales and marketing functions.

In April 2006, Torii also extended its manufacturing operations to include those of JT.

This partnership has enabled JT and Torii to continuously supply highquality pharmaceutical products.



## Sales and Marketing

Torii has about 300 medical representatives (MRs) working at seven branch offices throughout Japan. In order to distribute information relating to pharmaceutical products, the MRs use Torii's marketing support system to access the information they need to provide prompt responses to specific needs. This marketing support system is crucial to effective information distribution, and also enhances clients' confidence in Torii through disseminating information widely shared by MRs and other business units to medical professionals.

The Pharmaceutical Marketing & Promotion Group formulates business strategies based on analyses of market needs and projections of future changes in the market environment. It also supports initiatives to enhance the quality of the pharmaceutical information that MRs provide to

In principle, new ethical pharmaceutical products developed by JT are marketed in Japan by Torii, which is strengthening its marketing and distribution system in preparation for the introduction of new drugs.

Torii also works actively with JT to in-license products that can be brought to the Japanese market.

## Manufacturing

We outsource the entire process of pharmaceutical production. As a pharmaceutical company, in cooperation with our contract manufacturers, we work daily to fulfill our responsibility to ensure the quality and stable supply of our products.

Highly sophisticated quality assurance and safety management systems are required for pharmaceutical products that directly affect people's lives and health.

We have built a strong system of cooperation with pharmaceutical manufacturing sites and established a thorough quality management system of pharmaceutical products to maintain quality throughout all of our manufacturing processes and provide customers with an invisible feeling of reassurance. Each and every one of our employees is constantly aware that beyond the pharmaceutical products we manufacture, there are the patients and their families who need these products.

In order to provide pharmaceutical products that patients can use with the utmost confidence, we regularly visit pharmaceutical manufacturing sites to confirm manufacturing control and quality control with our own eyes.

Under the quality control system based on Good Manufacturing Practices (GMP)\*, manufacturing sites produce pharmaceutical products while confirming quality for each process, conduct the prescribed tests, and release only those that pass the tests.

We also share information regarding product quality with each manufacturing site to implement process improvements and quality improvements on a

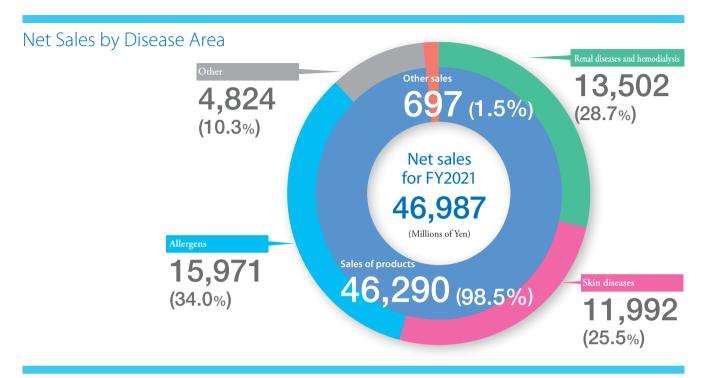
\* Standards for manufacturing control and quality control of pharmaceutical products

## Research and Development

In the allocation of functions concerning R&D with JT, R&D functions for novel compounds are concentrated at IT.

JT is actively investing business resources to enhance and strengthen its R&D capabilities, aiming to create innovative, original drugs by building up a unique, world-class pharmaceutical business driven

JT's Central Pharmaceutical Research Institute consists of six specialized research facilities that collaborate closely on new drug R&D in the Group's priority areas: (1) glucose and lipid metabolism, (2) immune disorders and inflammation, and (3) virus research.



## Mainstay Products

\*In-house products



Riona Tablets Therapeutic agent for hyperphosphatemia/ Therapeutic drug for iron deficiency anemia (IDA)

FY2020 FY2021 46,507 million ¥6,863 million



ANTEBATE\*





Oral antipruritic agent FY2021









FY2021 ¥1,291 million ¥4,025 million



MITICURE House Dust Mite Sublingual Tablets\* House dust mite allergy (allergen immunotherapy)

Net sales			
FY2020		FY2021	
44,776 million		¥ <b>7,386</b> million	

## Corporate Governance

#### Basic Stance toward Corporate Governance

At Torii, corporate governance means the structure to enable the Company to respond to changes in the business environment quickly and appropriately and to conduct fair and transparent management to achieve sustainable growth of the Company and enhance corporate value over the medium to long term under Torii Pharmaceutical's Purpose, the corporate philosophy, and 4S MODEL, the basic management stance.

We recognize that the enhancement of corporate governance will lead to the Company's sustainable growth and medium- to long-term improvement in corporate value.

While respecting the Group management policy of JT, Torii's parent company, Torii aims to ensure management autonomy and independence as a listed company.

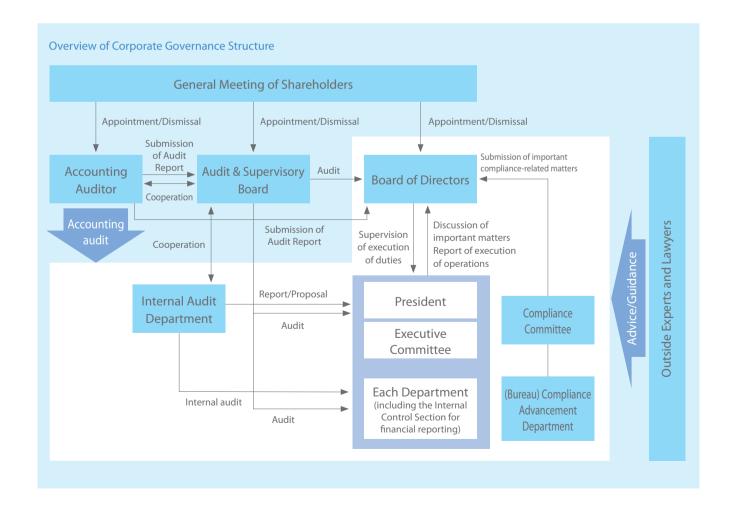
Based on the stance described above, we have defined the Corporate Governance Policy and are working to achieve effective corporate governance.

#### Corporate Governance Structure

The corporate governance organs adopted by Torii under the Companies Act of Japan include the General Meeting of Shareholders, the Directors, the Board of Directors, the Audit & Supervisory Board Members, the Audit & Supervisory Board and the accounting auditors. Moreover, with the aim of separating management decision-making and supervision from business execution, the Company has introduced an executive officer system and delegated appropriate authority to Executive Officers from the viewpoint of ensuring swift decision-making concerning business execution.

In addition, the Company has established the Executive Committee, the Compliance Committee, the Compliance Advancement Department and the Internal Audit Department from the perspective of building an effective corporate structure and has appointed Independent Outside Directors and Independent Outside Audit & Supervisory Board Members in order to enhance corporate governance through operation and maintenance of the basic policies regarding the development of internal control system.

Below is an overview of our corporate governance structure.





#### Overview of Corporate Governance

Organization format	Company with Audit & Supervisory Board
Chairperson of the Board of Directors	Non-Executive Director
Number of Directors*	3 (including 2 Outside Directors)
Number of Audit & Supervisory Board Members*	3 (including 2 Outside Audit & Supervisory Board Members)
Appointment of Independent Officers*	2 Outside Directors, 2 Outside Audit & Supervisory Board Members
Number of Board of Directors meetings in 2021	14 times
Number of Audit & Supervisory Board meetings in 2021	14 times

Remuneration for Each Director	Executive Director compensation consists of monthly remuneration and bonuses based on positions. The bonus is granted based on the achievement of the individual and business performance. Non-Executive Director compensation, on the other hand, consists of monthly remuneration based on positions. Directors (other than Outside Directors) are also subject to the Restricted Stock Compensation Plan as a medium- and long-term incentive.
Remuneration for Each Audit & Supervisory Board Member	Monthly remuneration based on full-time/part-time member status
Accounting Auditor	Deloitte Touche Tohmatsu LLC

<sup>\*</sup> Information as of March 29, 2022.

#### Evaluation of Effectiveness of the Board of Directors

In fiscal 2021, Torii evaluated the effectiveness of the Board of Directors by sending a questionnaire to all Directors and Audit & Supervisory Board Members. Items for evaluation included the contents of materials, explanations of agenda items, deliberation on agenda items, communication, the way in which meetings are held, etc. Questionnaire results as summarized by Independent Outside Directors showed that each item for evaluation was regarded as generally reasonable and appropriate. However, in view of the impact of the COVID-19 pandemic, some opined that communication between Directors, Audit & Supervisory Board Members, and Executive Officers, needs to be further enhanced. Based on these results, we will implement further improvements.

#### Matters with Possible Significant Impact on Corporate Governance

#### Collaboration with Japan Tobacco Inc. (JT)

JT is Torii's parent company and owns 54.88% of Torii's voting shares.

Torii and its parent company JT (specifically, the pharmaceutical division of the company) 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. The allocation of functions is for the purpose of optimization to realize our corporate philosophy. Also, this enables us to conduct appropriate business activities by ensuring a certain level of independence while also maintaining close cooperation with the parent company.

The parent company does not apply restrictions such as approval requirements to Torii's business activities. The parent company has dispatched 44 of its employees (as of December 31, 2021) to Torii with the aim of improving the efficiency of business operations and enhancing management. However, since these employees were dispatched in response to Torii's request, Torii believes it is able to make independent management decisions.

#### Parent Company's Policies on Group Management

The policies of JT, Torii's parent company, on Group management are as follows:

JT aims for the Group's sustainable profit growth and increase of corporate value over the medium to long term in pursuit of the 4S model, its management principle, by sharing and practicing the Group mission on a group-wide basis.

Based on its belief that better corporate governance contributes to achieving the aforementioned goals, JT strives to optimize the Group structure by defining functions and regulations shared in the Group and managing the Group as a whole. In addition, JT coordinates compliance (including the internal reporting system), internal auditing, assurance of reliability of financial reporting and more with its subsidiaries and maintains these activities.

JT strives to give the best consideration to assure the independence of its listed subsidiary and to respect the rights of minority shareholders.

## Directors and Audit & Supervisory Board Members



Representative Director, President and Chief Executive Officer

#### Goichi Matsuda

Apr. 1990 Joined Japan Tobacco Inc

Jan. 2009 Vice President, Planning Dept., Soft Drink Business Division, Food Business Headquarters of Japan Tobacco Inc.

Jun. 2009 Member of the Board Director of JT Beverage Inc Jul. 2010 Vice President, Planning Dept., Soft Drink Business Division of

Japan Tobacco Inc. Jul. 2012 Senior Manager, Soft Drink Business Division of Japan Tobacco Inc.

Jul. 2012 Member of the Board, Senior Vice President of Japan Beverage Holdings Inc.

Jun. 2013 Senior Vice President, Head of Beverage Business, of Japan Tobacco Inc. Jun. 2013 Member of the Board, Director of JT Beverage Inc.

Jan. 2016 Senior Vice President, Deputy President, Pharmaceutical Business of Japan Tobacco Inc.

Jan. 2017 Corporate Advisor of Pharmaceutical Division of Japan Tobacco Inc. Mar. 2017 Member of the Board, Director, Deputy Head of Pharmaceutical Marketing & Promotion Group and Vice President, Marketing Planning Dept. of the Company

Mar. 2019 Representative Director, President and Chief Executive Officer of the Company (current position)

#### Member of the Board, Director (Outside)

#### Masao Torikai

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Apr. 1994 Registered as lawyer (The Dai-ichi Tokyo Bar Association) Joined Momo-o, Matsuo & Namba

Sept. 2000 Registered as lawyer in New York State

Jan. 2002 Partner of Momo-o, Matsuo & Namba (current position) Jun. 2010 Audit & Supervisory Board Member of the Company

Jun. 2013 Member of the Board, Director of the Company (current position)

#### Member of the Board, Director (Outside)

#### **Toshio Fukuoka**

2

Joined Tokyo Regional Taxation Bureau Retired from the position of District Director of KawasakiKita Tax Office

3

6

Aug. 2015 Registered as tax accountant, established Toshio Fukuoka Tax Accountant Office, Representative (current position)

Mar. 2016 Audit & Supervisory Board Member of the Company Jun. 2016 Outside Audit & Supervisory Board Member of FUJI FURUKAWA

ENGINEERING & CONSTRUCTION CO. LTD. (current position) Mar 2018 Member of the Board, Director of the Company (current position)

#### Standing Audit & Supervisory Board Member

## **Ken Yamamoto**

Apr. 1984 Joined Japan Tobacco and Salt Public Corporation (currently

Apr. 2005 Senior Manager of Business Planning Dept., Pharmaceutical Division of Japan Tobacco Inc.

Senior Manager of Business Administrative Dept., Pharmaceuti-cal Division of Japan Tobacco Inc. lan 2016

Mar. 2016 Vice President of Accounting Dept. of the Company

Jan. 2017 Senior Vice President, Accounting Dept. of the Company Mar. 2018 Executive Officer, Accounting Dept. of the Company

Oct. 2019 Executive Officer, Finance & Accounting Dept. of the Company

Mar. 2020 Audit & Supervisory Board Member of the Company (current

#### Audit & Supervisory Board Member (Outside)

#### Eiichi Izumo

Inc. (current position)

Joined Tohmatsu & Co. (currently Deloitte Touche Tohmatsu LLC) Registered as certified public accountant

Jul. 2010 Partner of Deloitte Touche Tohmatsu LLC Established Izumo CPA Office, Representative (current position) Feb. 2015 Outside Audit & Supervisory Board member of Benesse Holdings,

Mar. 2016 Audit & Supervisory Board Member of the Company (current

Sep. 2020 Outside Audit and Supervisory Board Member of Lasertec Corporation (current position)

#### Audit & Supervisory Board Member (Outside)

#### Takaharu Matsumura

Oct. 2000 Registered as lawyer (Tokyo Bar Association) Jun. 2002 Joined New Tokyo International (later Bingham Sakai Mimura Aizawa – Foreign Law Joint Enterprise through office consolidation)

Apr. 2010 Partner of Bingham Sakai Mimura Aizawa – Foreign Law Joint Enterprise

Apr. 2015 Partner of Anderson Mori & Tomotsune (currently Anderson Mori & Tomotsune Foreign Law Joint Enterprise) through office

consolidation (current position) Apr. 2017 Outside Audit & Supervisory Board Member of PROPOLIFE

Audit & Supervisory Board Member of the Company (current Mar. 2018

## **Executive Officers**

Senior Executive Officer	Head of Innovation Group	Atsuyuki Kakee
Senior Executive Officer	Head of Pharmaceutical Marketing & Promotion Group	Katsunobu Fujiwara
Senior Executive Officer	Head of Planning & Administration Group	Nobumasa Kondo
Executive Officer	Head of Production Group	Masaki Sunami
Executive Officer	Head of Pharmacovigilance & Quality Assurance Group	Noriaki Nishino

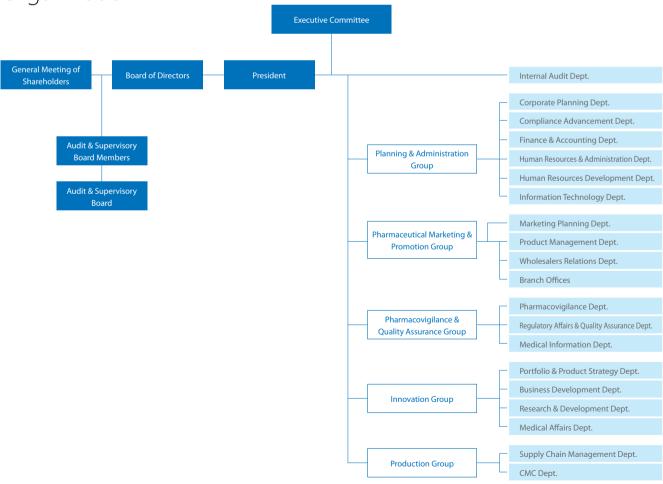
## Skill Matrix

The Board of Directors and the Audit & Supervisory Board are composed of well-balanced members with knowledge, expertise, and experience in various fields in accordance with their respective roles and responsibilities in order to achieve sustainable growth and enhance corporate value of the Company over the medium to long term. In addition, the Company has introduced an executive officer system for the purpose of separating management decision-making and supervision from business execution.

The expertise, experience, etc. of each Director, Audit & Supervisory Board Member and Executive Officer are indicated in the table below.

	Name	Position	Responsibility	Corporate management / Management strategy	Legal affairs / Compliance / Risk management	Finance / Accounting	Sales / Marketing	Business development	Research and development	Quality	Certification
	Goichi Matsuda	Representative Director, President and Chief Executive Officer		•	•	•	•	•			
Directors	Masao Torikai	Member of the Board, Director (Outside)			•						Attorney at-law
	Toshio Fukuoka	Member of the Board, Director (Outside)				•					Tax accountant
Audit & Supervisory Board Members	Ken Yamamoto	Standing Audit & Supervisory Board Member		•		•					
	Eiichi Izumo	Audit & Supervisory Board Member (Outside)				•					Certified public accountant
Audi	Takaharu Matsumura	Audit & Supervisory Board Member (Outside)			•						Attorney at-law
Executive Officers	Atsuyuki Kakee	Senior Executive Officer	Head of Innovation Group and Vice President, Business Development Dept.	•				•	•		
	Katsunobu Fujiwara	Senior Executive Officer	Head of Pharmaceutical Marketing & Promotion Group	•			•				
	Nobumasa Kondo	Senior Executive Officer	Head of Planning & Administration Group	•	•	•					
Exec	Masaki Sunami	Executive Officer	Head of Production Group	•					•	•	
	Noriaki Nishino	Executive Officer	Head of Pharmacovigilance & Quality Assurance Group	•					•	•	Pharmacist





## **CSR** Initiatives

## **Our Responsibility to Customers**

We strive to improve the quality of life (QOL) of patients by supplying superior medicines and accurate information through medical professionals.

## Quality Management

#### **Quality Management Measures**

We have established a thorough quality management system for pharmaceutical products to maintain quality throughout all of our manufacturing processes and provide customers with the intangible value of reassurance. Each and every one of our employees is constantly aware that beyond the pharmaceutical products we manufacture, there are the patients and their families who need these products. To ensure that our employees maintain this mentality, we have formulated a Quality Assurance Policy, and conduct quality assurance operations in accordance with this policy.

- 1. We are attentive to the opinions and requests of customers and actively strive to improve the quality of our products.
- 2. We work closely with manufacturing sites to maintain a constant supply of products with stable quality.
- 3. We bring together our knowledge and experience to carry out quality assurance activities based on facts and data.

#### **Quality Assurance and Safety Control System**

In order to comply with various laws, ordinances, and regulations, we have established the three officers required by law for authorized pharmaceutical manufacturers (Chief Pharmaceutical Officer, Quality Assurance Manager, and Safety Manager) under the Officer responsible for pharmaceutical affairs. These three work closely together to thoroughly ensure the quality assurance and the safety of pharmaceutical products after their launch.

We perform quality assurance of pharmaceutical products through proper operation on a daily basis including making appropriate decisions on market release and managing and supervising domestic and overseas manufacturers responsible for manufacturing active ingredients, and handling quality information and quality defects.

Quality Assurance and Safety Control System



#### **GOP- and GMP-based Product Assurance**

GQP, which stands for Good Quality Practice, refers to standards that define the method of quality control of pharmaceutical products and stipulate the necessary operations for pharmaceutical manufacturers and distributors to ensure the quality of the products they manufacture and sell. GMP, short for Good Manufacturing Practice, refers to standards for manufacturing control and quality control of pharmaceutical products and defines the requirements for pharmaceutical products manufacturing sites to ensure that pharmaceutical products are consistently produced and controlled in accordance with quality standards.

Under the GQP-based control system, Torii regularly visits manufacturing sites that manufacture drug substances and formulations to confirm manufacturing control and quality control based on GMP. While sharing information regarding product quality with each manufacturing site on a daily basis, we are working to achieve process improvements and to further ensure stable quality with the aim of providing pharmaceutical products that patients can use with the utmost confidence.

#### **Response to Product Recall**

In the event of quality defects that require a pharmaceutical product recall, our highest priority is to ensure the safety of patients. Under the direction of the Chief Pharmaceutical Officer, we report to the administrative authorities, share information with medical institutions and other organizations, rapidly recall affected products, identify the cause of the issue, and implement improvement measures. We also review and revise supply schedules and provide information on alternative products to avoid inconveniencing the patients that use the pharmaceutical product in question.

#### Considerations for Packaging, Labeling and Individual **Product Boxes**

We consider and revise designs of packaging and labeling, reflecting information from medical institutions and patients as well as the industry guidelines. In order to increase visibility, identification, and convenience of individual product boxes, we engage in discussions with related divisions and make necessary improvements, such as change of the font size of text, incision of perforated lines on the boxes for scrapping, as desirable, for ease of disposal by medical institutions, and change of sealing tapes in accordance with the industry guidelines.

## Stable Supply

#### **Stable Supply Measures**

Providing a stable supply of pharmaceutical products is one of the most important missions of companies that handle pharmaceutical products, on which people's lives directly depend.

Providing a stable supply of pharmaceutical products requires measures that encompass entire supply chains, and involve Torii itself and numerous partners responsible for every phase from the procurement of drug substances (active pharmaceutical ingredients) and other raw materials to manufacturing of pharmaceutical products, inventory optimization, and logistics.

We have put in place systems in preparation for various contingencies, including procurement of drug substances and raw materials from multiple suppliers. We are striving to ensure stable supply to provide the amounts of pharmaceutical products needed, when needed, where needed.

#### **Measures for Managing Logistics while Ensuring Quality**

To fulfill our duty as a pharmaceutical company, we have built a system ensuring stable supply of safe, high-quality pharmaceutical products manufactured under strict quality control.

With regard to temperature control, our logistics center stores pharmaceutical products in a refrigerated or room-temperature warehouse in accordance with the temperature control category (refrigerated storage or room-temperature storage) defined for each pharmaceutical product.

For management of logistics, we exclusively use dedicated temperaturecontrolled vehicles for pharmaceutical product transport and regularly monitor temperature of the vehicles for thorough quality control during transport.

With regard to risk management, anticipating the possibility of a large-scale disaster, we operate two logistics centers, one in East Japan and the other in West Japan. Under this system, if one center is affected by the disaster, the other center can continue to supply pharmaceutical products.

## Appropriate Information Provision

#### Information Collection and Provision

Torii strives to promote the proper use of pharmaceutical products, and through our MRs we collect safety information from medical professionals such as data on side effects.

The information we collected and analyzed is provided on an ongoing steady basis as feedback to medical professionals, contributing to the safe and effective use of pharmaceutical products by patients.

We also participate in relevant academic society meetings and update product information sites for medical professionals to provide a wide range of information on the proper use of pharmaceutical products.

#### **Promotion of Proper Use**

In order to ensure safer use of pharmaceutical products, we constantly collect safety information such as on side effects. We evaluate and analyze the safety information collected, and when the results indicate the need for additional information on proper use, we revise the risk management plan (RMP) and drug package inserts and update the drug information. We have implemented measures so that our pharmaceutical products are used more safely by notifying medical professionals of the contents of these revisions.

#### Measures through MRs

The mission of our MRs is to accurately convey various information on pharmaceutical products to medical professionals, collect information such as that on the safety of products after launch, and provide information on proper use obtained as a result of the evaluation and analysis of this information by the Pharmacovigilance Department to medical professionals. This helps ensure that pharmaceutical products are used properly.

MRs work to promote the proper use of pharmaceutical products for the sake of patients by providing information to medical professionals as well as collecting information from them.

#### **MR Education and Training**

We carry out a range of education and training programs to ensure that our MRs properly provide information on our pharmaceutical products to medical professionals and collect their feedback.

Various divisions of Torii collaborate in human resource development of MRs so that they can earn the trust of medical professionals. Practical training is designed to cultivate a mindset attuned to attending to the needs of individual patients and developing the ability to propose the optimum treatment for the patient.

## Customer Support Department

#### **Customer Support Department Initiatives**

Our Customer Support Department interfaces directly with medical professionals, patients, and their families, handling a broad range of inquiries.

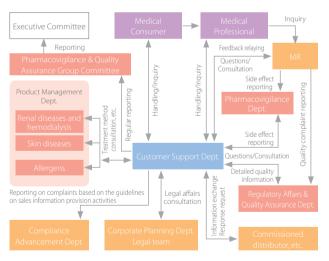
No matter how excellent a pharmaceutical product may be, it is only effective when used properly. To this end, we have worked to provide highquality, appropriate, science-based drug information that takes into account the needs of our customers.

#### **Sharing Customer Feedback within the Company**

As an open corporate contact point with customers, the Customer Support Department shares questions and opinions from customers with corresponding divisions, enabling them to consider future actions based on the latest information on safety, interaction, usage method and others.

In order to meet customers' expectations, we will continue to reflect customer feedback in product improvements and the provision of highquality information, contributing to patients' health.

#### System for Sharing Information within the Company

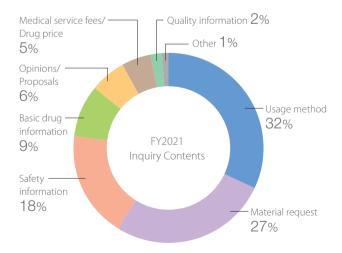


#### **Customer Support Education**

We participate in external training related to customer service both inside and outside the pharmaceutical industry, to ensure that each and every customer is treated with integrity. Staff members who deal with customers are trained using the same continually updated materials as are used by MRs, and participate actively in study sessions held by related divisions, workshops, and academic society meetings so that they understand the latest drug information. This enables them to provide customers with accurate, appropriate information.

#### Communication and Awareness-Raising through the Website "Health Information" Section and Pamphlets for Patients

The "Health Information" section of our website provides health-related information such as information regarding disease mechanisms and symptoms. We have created websites such as "Touseki no Kayumi (Dialysis Pruritus).jp" and "Torii-san's Allergen Immunotherapy Navigation," through which we provide information to foster an accurate understanding of disorders. Furthermore, we have created PDF versions of pamphlets such as "Jozuna Rin to Kalium no Torikata (How to Efficiently Control Intake of Phosphorous and Potassium" and "Kichin-to Shirou Atopic Dermatitis (Atopic Dermatitis Navigation)," which are available on our website. We provide this information to help patients deepen their understanding of diseases, their treatments, and points to remember in everyday life, in order to contribute to the health of patients.



## **CSR** Initiatives

## Our Responsibility to Shareholders

We disclose timely, accurate corporate information and endeavor to generate appropriate shareholder returns and improve our corporate value.

#### Information Disclosure

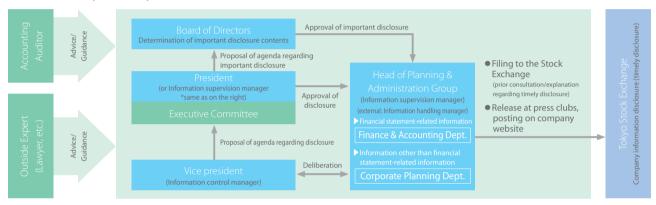
#### **Information Disclosure Measures**

#### Communication with our shareholders and investors

In order to promote dialogue with our shareholders and investors, Torii holds individual consultations upon request, as well as endeavors to disclose information in a timely and appropriate manner by posting financial

highlights, financial results, securities reports, annual reports, press releases, and other information on the Torii website.

Overview of Torii's Timely Disclosure System



## Dividend Policy

Torii's basic policy is to distribute its surplus dividends in a stable and continuous manner based on the understanding that generating appropriate shareholder returns is one of the key roles of management.

Torii's basic approach is to pay surplus dividends twice per year in the form of an interim dividend and a year-end dividend. The interim dividend is decided by the Board of Directors, and the year-end dividend is decided by the General Meeting of Shareholders. The Articles of Incorporation of Torii stipulate that interim dividends may be decided by resolution of the Board of Directors.

At the 130th General Meeting of Shareholders, held on March 29, 2022, it was resolved that Torii will pay a year-end dividend of ¥24 per share for the current fiscal year. Together with the ¥24 per share paid in interim dividends, this amounts to an annual dividend of ¥48 per share.

Surplus dividends whose record date falls within the current fiscal year are as follows.

Resolution date	Total dividends (Millions of Yen)	Dividend per share (Yen)
July 30, 2021 Resolution by Board of Directors meeting	674	24
March 29, 2022 Resolution by General Meeting of Shareholders	674	24

The business environment surrounding the pharmaceutical industry is rapidly changing. In order for Torii to continue to fulfill its responsibility to stakeholders, it is becoming increasingly necessary for Torii to continue to create new drugs that meet medical needs. Torii recognizes that it needs to continue to make investments that will contribute to future growth as a top priority, including the acquisition of new in-licensed drugs. In particular, during the period of the Medium-Term Management Plan 2022-2024, Torii will be more aggressive than before in its efforts regarding in-licensed drugs and will use retained earnings to aggressively promote business investments.

Regarding shareholder returns for fiscal 2022, in addition to the basic policy of distributing dividends in a continuous and stable manner, Torii will continue to pay the same level of dividends as in previous years, while considering business investments for future growth more aggressively than before.

## **CSR** Initiatives





We strive to mitigate global warming as we maintain a high ethical standard regarding our corporate social responsibility through business activities that reflect the needs of society in order to be a good corporate citizen.

#### Torii Pharmaceutical Environmental Charter

#### **Basic Policy on the Environment**

As a company aspiring to contribute to the health and happiness of people through pharmaceutical products, Torii Pharmaceutical considers protection of the global environment to be an important issue and conducts business activities with environmental protection in mind.

#### **Code of Conduct**

- 1. Throughout our business activities from R&D to production, distribution, provision of information on pharmaceutical products, and sales, we comply with environmental laws and regulations applicable to our operations and internal rules. At the same time, we recognize the impact of our operations on the environment and strive to reduce it.
- 2. Upon grasping and understanding the Environmental Action Plan, we actively collaborate on company-wide measures concerning environmental issues in addition to engaging in the environmental initiatives of our own departments.
- While promoting resource saving and energy saving and endeavoring to realize a low carbon society, we strive to reduce waste and facilitate recycling.
- We monitor industrial waste processors to which disposal is consigned, raw materials suppliers, etc. to confirm their compliance with laws and regulations and their initiatives for environmental issues.
- We actively collaborate on company-wide social contribution activities in addition to engaging in the social contribution activities of our own departments.
- We also strive to take action concerning environmental issues and endeavor to make social contributions in our private lives.

#### Environmental Action Plan





		FY2021 Environmental Action Plan	FY2021 results	Evaluation	FY2022 Environmental Action Plan
Greenhouse gas emissions reductions	Head office	FY2021 target: 326 t-CO₂ or less  [Main measures]  ■ Continue installing energy-saving vending machines  ■ Continue implementing Cool Biz and Warm Biz energy-saving initiatives	FY2021 result: 323 t-CO <sub>2</sub> Vs. FY2021 target: 0.9% reduction [Measures implemented]  Continued installing energy-saving vending machines  Continued implementing Cool Biz and Warm Biz energy-saving initiatives	<b>©</b>	FY2022 target: 328 t-CO <sub>2</sub> or less [Main measures]  © Continue installing energy-saving vending machines and review the number of vending machines installed  © Continue implementing Cool Biz and Warm Biz energy-saving initiatives  © Strengthen initiatives for paperless operation
	Sales vehicles	FY2021 target: 974 t-CO₂ or less  [Main measures]  ■ Continue selecting fuel-efficient vehicles such as hybrids  ■ Continue promotion of eco-drive awareness and education activities  ■ Introduce telematics to reduce fuel consumption by minimizing sudden start, sudden braking, etc.	FY2021 result: 874 t-CO <sub>2</sub> Vs. FY2021 target: 10.3% reduction [Main measures]  © Continued selecting fuel-efficient vehicles such as hybrids  Continued promotion of eco-drive awareness and education activities  Introduced telematics to reduce fuel consumption by minimizing sudden start; sudden braking, etc.	<b>©</b>	FY2022 target: 874 t-CO₂ or less  [Main measures]  ■ Continue selecting fuel-efficient vehicles such as hybrids  ■ Continue promotion of eco-drive awareness and education activities  ■ Introduce telematics to reduce fuel consumption by minimizing sudden start, sudden braking, etc.
Maintain/increase waste recycling rate	Head office	FY2021 target: 97% or above [Main measures] ■ Continue to consign disposal to industrial waste processors with high recycling rates ■ Continue selling off items with value	FY2021 result: 98.5% [Measures implemented]  ■ Continued to consign disposal to industrial waste processors with high recycling rates  ■ Conducted monitoring of industrial waste processors  ■ Continued selling off items with value	<b>©</b>	FY2022 target: 98% or above  [Main measures]  ■ Continue to consign disposal to industrial waste processors with high recycling rates and continue monitoring of industrial waste processors  ■ Continue selling off items with value

## Overview of Business Activities and Their Environmental Impacts

#### Total energy usage

Electricity: 1,023,000 kWh City gas: 3.600 m<sup>3</sup> Gasoline: 377 kL

#### Offices

Planning and administration, Information systems, General office work, sales

#### Waste and generation of items with value

Total waste discharge: 22.0 t Items with value sold: 0.0 t Recycling volume: 21.7 t Final disposal volume:

**Emissions into the atmosphere** 

CO<sub>2</sub>: 1,311 t

## Compliance Measures

#### Response to the Violation of the Antimonopoly Act

In March 2020, Torii received a cease and desist order and a surcharge payment order from the Japan Fair Trade Commission (JFTC) pursuant to the Antimonopoly Act for a violation of the Antimonopoly Act concerning the setting of the wholesale price of the CALVAN Tablets. Taking these orders gravely and seriously, we revised the Code of Conduct and established and notified the guidelines as measures to prevent recurrence. We are holding regular training sessions and continuing implementation of strengthened supervisory functions in order to keep the need for vigilance at the forefront of our minds. We will continue our efforts to ensure thorough compliance with laws and regulations in order to prevent recurrence and restore trust as soon as possible.

#### **Compliance as a Pharmaceutical Company**

Pharmaceutical companies are required to constantly maintain a high level of ethics and transparency in their corporate activities.

Torii has defined various internal standards such as the Torii Pharmaceutical Promotion Code based on the JPMA Code of Practice by the Japan Pharmaceutical Manufacturers Association and the guidelines on sales information provision activities by the Ministry of Health, Labor and Welfare, and engages in complianceoriented activities.

#### **Compliance Promotion Structure**

Torii positions ensuring compliance as one of the foundations for business operation. In order to ensure heightened effectiveness, we formulated rules for the compliance structure and established the Compliance Committee. Chaired by the President, this committee directly reports to the Board of Directors and deliberates on compliance promotion issues.

The Compliance Advancement Department, which spearheads company-wide compliance promotion operations, also supervises Torii's sales information provision activities in response to the guidelines on sales information provision activities, which came into force in 2019. The department screens Torii's academic information materials and monitors information provision activities to confirm whether the information provision activities are in compliance with the guidelines. The department also conducts review of research support for academia.

#### **Employee Awareness-Raising and Education**

Torii defines compliance as maintaining the trust of stakeholders and not disappointing them. To this end, we distribute a compliance book that defines concrete action standards serving as guidelines for specific actions as well as values and ethics that all employees should share, and we engage in education and awareness-raising activities on a continual basis. We conduct compliance training in our new employee training and new General Manager training programs, and we hold two study sessions per year in each of our company's divisions to thoroughly ingrain compliance throughout the Company.

Furthermore, we implement drug injury education for all employees to deepen the knowledge of drug-related injuries and foster awareness on patients' use of drugs.

#### **Compliance Questionnaires**

We administer compliance questionnaires every two years to understand and evaluate employees' attitudes towards compliance, current company and workplace compliance conditions, and compliance implementation conditions, and we use

these findings in our future compliance promotion activities.

The results of these questionnaires are posted for viewing by all employees on our company intranet. The issues identified through these questionnaires are also used as topics in our compliance study sessions.





Compliance Book

Compliance Card

#### **Reporting and Consultation Contact Point (Hotline)**

We have established an internal reporting and consultation desk and an external reporting contact point (lawyer) for compliance issue reporting and consultation. We strive to promptly identify and minimize the threats posed to the company by legal violations. In addition to our company-wide reporting and consultation desk, we have also established consultation desks within individual groups to better facilitate consultation.

## Transparency Initiatives

Collaboration with universities and other research institutions and medical institutions is vital and essential for us to contribute to peoples' health as a pharmaceutical company.

During the course of these activities, we sometimes pay medical institutions compensation for their contributions, and we believe that we must maintain transparency in our relationships with them. We also believe that we must guarantee transparency in the relationships between patient groups and pharmaceutical companies so that the opinions and input from patients and supporters can be sufficiently leveraged within medical treatment as a social resource.

Based on this philosophy, we have defined Transparency Guideline for the Relation between Corporate Activities and Medical Institutions and Transparency Guidelines for the Relation between Corporate Activities and Patient Groups. We will fulfill our responsibility to society through our activities, which are based on these guidelines.

## **CSR** Initiatives

## **Our Responsibility to Employees**

We aim to motivate all our employees and offer them every opportunity to achieve fulfillment by respecting every individual, ensuring equal opportunities for career advancement, and treating employees fairly on the basis of unbiased assessments.

#### **Human Resources Development**

To reinforce our organizations, we offer not only position-specific training but also elective training for which employees apply as well as distance learning programs focused on the business skills that we believe employees need to conduct their work, continuously implementing measures that support and promote employees' self-led development.

Training programs for managerial personnel are designed to enhance their human resources development- and management-related skills and knowledge in areas such as subordinate development, encouragement of departments and teams, and appropriate evaluation. In tandem with e-learning, we are conducting ongoing, systematic personnel development.

Training Participation Results (Fiscal 2021)

Learning and training	Number of participants
Life planning training (information provision)	16 [31]
Topic-specific training (business basics, team power, global)	11 [14]
Management training (including e-learning)	435 [228]
Position-specific training (excluding new employee training)	81 [97]
New employee training	12 [0]
Distance learning/e-learning (self-improvement)	124[356]

Note: Figures in brackets are the previous year's figures.

## Creating Better Working Environments

#### Measures for Realizing Working Environments in which **Each and Every Employee Works Enthusiastically**

For Torii to achieve sustainable growth and enhancement of corporate value over the medium to long term, flexible and swift actions are required. For this purpose, we aim to realize inclusive environments where each and every employee can work on their own initiative and work flexibly. Our goal is for each and every employee to work independently and autonomously with awareness. We aim become an enabling organization by offering organizational support to employees through the Company's systems and raising awareness.

As one of the measures of this initiative, we have also formulated an action plan based on the Act on Promotion of Women's Participation and Advancement in the Workplace.

Status of Measures for Promoting Active Participation by Female Employees

ltem	As of December 31, 2021
Percentage of women in management positions	10.0% [9.9%]
Percentage of women in all employees	22.1% [21.8%]
Percentage of women in newly hired employees	42.9% [44.4%]
Average years of service between Male vs Female	Men: 14.6 years Women: 11.2 years
	[Men: 13.8 years Women: 10.8 years]
Average overtime per month	17.6 hours [14.5 hours]
Rate of taking annual paid leave (April 2021 to March 2022)	68.4% [59.1%]

Note: Figures in brackets are the previous year's figures.

#### **Human Rights Measures**

We believe it is important that people working in the same workplaces respect one another and build relationships of mutual trust, and that as members of society all people always respect the rights of others. This is why on December 10, Human Rights Day, we carry out measures aimed at developing a shared awareness of human rights throughout workplaces and heightening respect for human rights. These measures include familiarizing employees with pamphlets created by the Human Rights Bureau of the Ministry of Justice containing information regarding human rights issues and initiatives.

#### **Occupational Safety and Health**

Each of our work sites carries out safety and health measures in order to achieve safe and healthy work environments.

In addition to the holding of a monthly meeting of the Safety and Health Promotion Committee, the head office carries out Health Officer inspections (once per week), Industrial Physician inspections (once per month), and Safety and Health Committee inspections (held for each floor five times per year), and labor and management work to improve workplace environments through deliberations at Head Office Safety and Health Committee meetings held each month.

Company-Wide Safety and Health Control Organizations



- \* A Safety and Health Committee is established for worksites with 50 or more full-time
- \* A Health promoter officer is appointed for worksites with 10 or more but less than 50 full-time workers.

# Financial Section

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# Ten-Year Financial Summary

	Millions of Yen							
_	Marc	ch 31	December 3	31				
	2013	2014	2014*2	2015				
For the Year								
Net sales	¥52,294	¥58,109	¥43,504	¥62,378				
Gross profit	29,452	31,842	22,917	31,564				
Operating income	2,794	4,987	4,032	4,919				
Income before income taxes	2,929	5,133	3,781	5,258				
Net income	1,849	3,352	2,419	3,527				
Capital expenditures	1,374	1,202	1,514	2,207				
Research and development costs	7,824	6,662	3,400	5,237				
Net cash provided by (used in) operating activities	151	(201)	(609)	4,940				
Net cash provided by (used in) investing activities	874	17,706	499	957				
Net cash used in financing activities	(1,181)	(1,319)	(1,410)	(1,582)				
At Fiscal Year-End								
Total assets	¥91,350	¥93,137	¥92,550	¥98,868				
Total equity	76,700	79,018	80,225	82,826				
Number of shares issued (Thousands)	28,800	28,800	28,800	28,800				
Number of employees	969	1,009	1,047	1,058				
		Yen						
Per Share Data								
Total equity	¥2,710.2	¥2,792.1	¥2,834.8	¥2,926.8				
Net income	65.4	118.5	85.5	124.7				
Cash dividends	40	40	40	48				
		%						
Key Ratios								
Operating income ratio	5.3	8.6	9.3	7.9				
Return on equity (ROE)	2.4	4.3	3.0	4.3				
Return on assets (ROA)	2.1	3.6	2.6	3.7				
Shareholders' equity ratio	84.0	84.8	86.7	83.8				
Dividend payout ratio	61.2	33.8	46.8	38.5				
	<del></del>							

<sup>\*1</sup> All dollar figures in this report refer to U.S. currency. Dollar figures in this report have been translated from yen, for convenience only, at the rate of ¥115.02=US\$1.00, the approximate exchange rate prevailing

<sup>\*2</sup> Fiscal year 2014 was a nine-month period from April 1, 2014 to December 31, 2014 due to a change in the Company's fiscal year-end.

		Millio	ns of Yen			Thousands of U.S. Dollars*1
					December 31	December 31
2016	2017	2018	2019	2020	2021	2021
¥60,206	¥64,135	¥62,551	¥42,998	¥41,700	¥46,987	\$362,548
29,919	32,841	30,707	22,295	21,737	24,338	188,991
3,819	6,281	4,951	1,430	4,738	4,656	41,193
4,056	6,373	3,030	37,700	4,225	4,767	36,734
2,839	4,718	1,164	27,367	3,495	3,374	30,387
891	931	811	330	392	822	3,409
4,654	4,608	4,138	2,956	596	832	5,186
3,402	6,349	8,259	42,499	(3,443)	(156)	(29,936)
1,361	(7,593)	(27,068)	2,099	7,625	(1,498)	66,298
(2,289)	(1,546)	(1,432)	(1,433)	(1,425)	(1,546)	(12,394)
¥98,525	¥104,741	¥103,253	¥139,943	¥126,026	¥130,810	\$1,095,694
83,556	87,119	87,092	113,125	115,091	117,015	1,000,620
28,800	28,800	28,800	28,800	28,800	28,800	28,800
1,059	1,074	1,049	660	568	560	568
		,	Yen			U.S. Dollars*1
¥2,978.8	¥3,105.7	¥3,103.3	¥4,029.3	¥4,097.5	¥4,165.4	\$35.62
100.4	168.2	41.5	975.0	124.5	120.1	1.08
48	48	48	48	48	48	0.42
			%			
6.3	9.8	7.9	3.3	11.4	9.9	
3.4	5.5	1.3	27.3	3.1	2.9	
2.9	4.6	1.1	22.5	2.6	2.6	
84.8	83.2	84.3	80.8	91.3	89.5	
47.8	28.5	115.6	4.9	38.6	40.0	

## Management's Analysis of Financial Conditions, Operating Results and Cash Flows

#### Financial Results for the Year Ended December 31, 2021

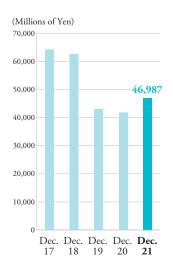
With regard to the business environment in which the pharmaceutical industry operated, business risks mounted because of the increasing difficulty of new drug development, a sharp rise in R&D costs, intensifying international competition, and other factors. In the Japanese market in particular, the industry faced severe conditions due to increasing requests to curb healthcare expenditures such as through the drastic reform of the NHI drug pricing system (including annual NHI drug price revisions) and encouragement of greater use of generic drugs. Furthermore, due to the spread of COVID-19, business activities were affected by the trend of limited consultations for patients at medical institutions and self-imposed restrictions on visits to medical institutions by medical representatives (MRs).

Under these conditions, Torii aimed to continue generating a positive operating income (excluding expenses relating to new business investments, which include investments to acquire new in-licensed drugs and M&A) and expand profit margins during the period covered by the Medium-Term Management Plan 2021. To this end, Torii has been tackling the following key issues under the Medium-Term Management Plan 2021: a. business structure reform, b. growth strategy, and c. maintaining the trust of stakeholders.

#### **Net Sales**

Despite the impact of NHI price revisions and a decrease due to the completion of production of items outsourced in line with the transfer of the Sakura Plant in July 2020, net sales increased by ¥5,287 million (12.7%) year on year to ¥46,987 million owing to such factors as increased sales volume in the allergens area and the launch of CORECTIM® Ointment (topical JAK inhibitor) in July 2020.

#### **Net Sales**

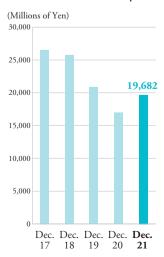


#### Sales of Mainstay Products

(Millions of Yen)

	Dec. 2020	Dec. 2021	Change
CEDARCURE	¥6,139	¥8,325	¥2,186
CLD/IICCOICL	10,137	10,323	35.6%
MITICURE	4,776	7,386	2,610
WITTCOIL	4,//0	/,300	54.6%
Riona	6,507	6,863	355
Kiona	0,507	0,003	5.5%
REMITCH	6,365	5.050	(1,306)
KEMITCH	0,303	5,058	(20.5)%
ANTEBATE	5,241	4,825	(415)
ANTEDATE	),4 <del>4</del> 1	4,823	(7.9)%

#### Selling, General and Administrative Expenses



Sales of mainstay products in franchise areas were as follows:

- In the renal disease and hemodialysis area, sales of Riona Tablets (a therapeutic agent for hyperphosphatemia and a therapeutic agent for iron deficiency anemia) increased by ¥355 million (5.5%) to ¥6,863 million. Sales of REMITCH (an oral antipruritic agent for hemodialysis patients) decreased by ¥1,306 million (20.5%) to ¥5.058 million, affected by generic products in addition to the impact of NHI drug price revisions.
- In the skin disease area, sales of ANTEBATE (a topical corticosteroid) decreased by ¥415 million (7.9%) to ¥4,825 million, owing to the impact of NHI drug price revisions. Sales of CORECTIM Ointment increased by ¥2,733 million (211.7%) to ¥4,025 million.
- In the allergens area, sales of CEDARCURE Japanese Cedar Pollen Sublingual Tablets (allergen immunotherapy) increased by ¥2,186 million (35.6%) to ¥8,325 million, due to the further spread of allergen immunotherapy. Sales of MITICURE House Dust Mite Sublingual Tablets (allergen immunotherapy) increased by ¥2,610 million (54.6%) to ¥7,386 million.

#### Cost of Sales

Cost of sales increased by ¥2,687 million (13.5%) year on year to ¥22,649 million.

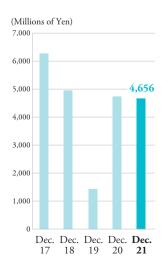
#### Selling, General and Administrative (SG&A) Expenses

Selling, general and administrative expenses increased by ¥2,682 million (15.8%) to ¥19,682 million, due mainly to increases in expenses associated with net sales and selling expenses in line with new product launches etc. as well as one-time expenses such as for computer upgrading.

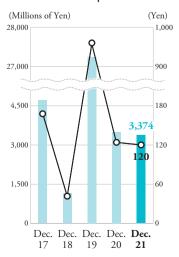
#### **Operating Income and Net Income**

As a result of the above, operating income was ¥4,656 million, a decrease of ¥81 million (1.7%) year on year. Net income was ¥3,374 million, a decrease of ¥120 million (3.5%).

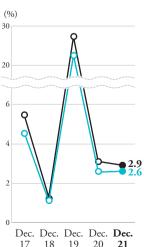
## Operating Income



#### ■ Net Income ◆Net Income per Share



#### -- Return on Equity (ROE) Return on Assets (ROA)



#### Financial Position at December 31, 2021

#### Assets, Liabilities and Equity

Total assets increased by ¥4,784 million (3.8%) from the end of the previous fiscal year to ¥130,810 million as of December 31, 2021. Current assets increased by ¥550 million (0.6%) to ¥97,292 million, mainly due to a ¥1,353 million increase in trade accounts receivable, a ¥1,256 million increase in finished products and merchandise, and a ¥354 million increase in raw materials and supplies, despite a ¥3,202 million decrease in cash and cash equivalents. Net property, plant and equipment increased by ¥300 million (16.9%) from the end of the previous fiscal year to ¥2,078 million mainly due to a ¥389 million increase in leased assets. Investment and other assets increased by ¥3,933 million (14.3%) from the end of the previous fiscal year to ¥31,439 million mainly due to a ¥2,155 million increase in long-term prepaid expenses and a ¥1,498 million increase in investment securities.

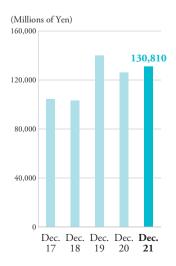
Total liabilities increased by ¥2,859 million (26.2%) to ¥13,795 million. Reasons for this change included a ¥1,495 million increase in income taxes payable, a ¥649 million increase in payables, and a ¥330 million increase in consumption tax payable included in Other Current Liabilities in Current Liabilities, and a ¥2,070 million decrease in payables.

Total equity rose by ¥1,924 million (1.7%) to ¥117,015 million. Contributing factors included surplus dividends of ¥1,348 million and net income of ¥3,374 million.

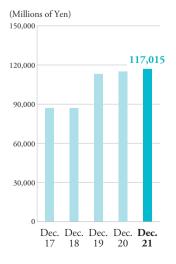
#### Cash Flows for the Year Ended December 31, 2021

At ¥58,374 million, cash and cash equivalents as of December 31, 2021 were ¥3,201 million (5.2%) lower than at the end of the previous fiscal year.

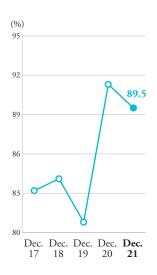
#### **Total Assets**



#### **Total Equity**



#### Shareholders' Equity Ratio



#### **Cash Flows from Operating Activities**

Net cash used in operating activities amounted to ¥156 million. (Net cash used in operating activities for the previous year totaled ¥3,443 million.) This result reflected an increase of ¥3,052 million in trade notes and accounts receivable, an increase of \(\frac{4}{2}\),155 million in long-term prepaid expenses, and an increase of \(\frac{4}{1}\),610 million in inventories, despite income before income taxes of ¥4,767 million and depreciation and amortization of ¥413 million.

#### **Cash Flows from Investing Activities**

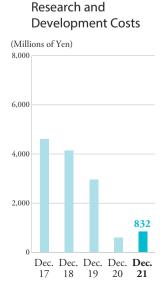
Net cash used in investing activities amounted to ¥1,498 million. (Net cash provided by investing activities for the previous year totaled ¥7,625 million.) Major items included inflows of ¥18,420 million in proceeds from sale and redemption of marketable securities and \(\frac{45}{360}\) million in proceeds from sale and redemption of investment securities. These inflows were offset by outflows of ¥14,900 million in purchases of marketable securities and ¥9,376 million in purchases of investment securities.

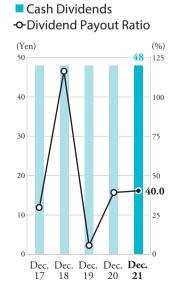
#### **Cash Flows from Financing Activities**

Net cash used in financing activities amounted to ¥1,546 million, consisting mainly of ¥1,348 million in dividends paid. (Net cash used in financing activities for the previous year totaled \(\frac{\pma}{1}\),425 million.)

#### Resources for Capital and Liquidity of Funds

Torii mainly requires funds for working capital to procure raw materials for the manufacturing of products, purchase merchandise, and secure goods, services, etc. for operating activities, as well as for strategic investments such as capital expenditures, acquisition of new in-licensed drugs to achieve sustainable growth, and co-development with JT. The Company procures these required funds from its own funds. With regard to the liquidity of funds, Torii secures liquid assets such as cash and deposits to be prepared for working capital and certain strategic investments.





## Balance Sheet

	Million	s of Yen	Thousands of U.S. Dollars (Note 1)
	December 31, 2021	December 31, 2020	December 31, 2021
ASSETS			
CURRENT ASSETS:			
Cash and cash equivalents (Notes 12 and 13)	¥ 58,374	¥ 61,576	\$ 507,518
Marketable securities (Notes 4 and 12)	7,198	8,528	62,580
Receivables (Note 12):			
Trade notes		7	
Trade accounts	20,302	18,949	176,509
Parent	1,754	119	15,257
Other	283	212	2,468
(Allowance for doubtful Accounts)		(2)	
Inventories (Note 5)	8,763	7,152	76,191
Prepaid expenses and other current assets	615	198	5,349
Total current assets	97,292	96,742	845,876
PROPERTY, PLANT AND EQUIPMENT:			
Land	344	344	2,994
Buildings and structures	3,310	3,343	28,778
Machinery and equipment	134	134	1,168
Furniture and fixtures	741	718	6,445
Lease asset (Note 11)	1,892	1,502	16,452
Construction in progress			8
Total	6,423	6,043	55,848
Accumulated depreciation	(4,345)	(4,265)	(37,770
Net property, plant and equipment	2,078	1,777	18,07
INVESTMENTS AND OTHER ASSETS:			
Investment securities (Notes 4 and 12)	22,309	20,810	193,957
Software	408	303	3,548
Long-term prepaid expenses	7,312	5,157	63,579
Deferred tax assets (Note 9)	641	587	5,579
Other long-term assets	767	647	6,675
Total investments and other assets	31,439	27,506	273,340
Total	¥130,810	¥126,026	\$1,137,288

	Millions	of Yen	Thousands of U.S. Dollars (Note 1)
	December 31, 2021	December 31, 2020	December 31, 2021
LIABILITIES AND EQUITY			
CURRENT LIABILITIES:			
Payable (Note 12):			
Trade accounts	¥ 4,084	¥ 3,929	\$ 35,510
Parent (Note 13)	1,761	1,274	15,313
Other	3,275	3,026	28,475
Current portion of long-term lease obligations (Note 11)	211	85	1,837
Income taxes payable (Note 12)	1,536	41	13,362
Accrued expenses	405	285	3,526
Accrued employees' bonuses	394	391	3,432
Accrued bonuses to directors and Audit & Supervisory Board members	13	13	118
Asset retirement obligations	14	42	122
Other current liabilities	674	370	5,867
Total current liabilities	12,372	9,461	107,565
LONG-TERM LIABILITIES:			
Liability for retirement benefits (Note 6)	837	948	7,280
Long-term lease obligations (Note 11)	275	209	2,393
Asset retirement obligations	53	59	468
Other long-term liabilities	256	256	2,229
Total long-term liabilities	1,423	1,473	12,372
EQUITY (Notes 7):			
Common stock—authorized, 54,000,000 shares; issued,			
28,800,000 shares in December 2021 and 2020	5,190	5,190	45,122
Capital surplus:	6,445	6,437	56,034
Additional paid-in capital	6,416	6,416	55,781
Other capital surplus	29	21	253
Stock acquisition rights (Note 8)		10	
Retained earnings:			
Legal reserve	1,297	1,297	11,280
Unappropriated	104,952	102,926	912,474
Unrealized gain on available-for-sale securities	523	636	4,554
Treasury stock—at cost, 707,605 shares in December 2021 and 714,558 shares in December 2020	(1,393)	(1,407)	(12,117)
Total equity	117,015	115,091	1,017,349
Total	¥ 130,810	¥ 126,026	\$ 1,137,288

## Statement of Income

	Millions	Millions of Yen		
	Year Ended December 31, 2021	Year Ended December 31, 2020	Year Ended December 31, 2021	
NET SALES	¥ 46,987	¥ 41,700	\$ 408,520	
COST OF SALES	22,649	19,962	196,919	
Gross profit	24,338	21,737	211,600	
SELLING, GENERAL AND ADMINISTRATIVE EXPENSES (Note 10)	19,682	16,999	171,118	
Operating income	4,656	4,738	40,481	
OTHER INCOME (EXPENSES):				
Interest and dividend income	281	275	2,448	
Loss on disposal of property, plant and equipment	(37)	(9)	(327)	
Business structure reform expenses (Note 14)	(12)	(736)	(105)	
Other—net	(130)	(41)	(1,135)	
Other income (expenses) —net	111	(512)	966	
INCOME BEFORE INCOME TAXES	4,767	4,225	41,448	
INCOME TAXES (Note 9):				
Current	1,396	49	12,143	
Deferred	(3)	680	(33)	
Total income taxes	1,392	729	12,109	
NET INCOME	¥ 3,374	¥ 3,495	\$ 29,338	
	Ye	n	U.S. Dollars	
PER SHARE OF COMMON STOCK (Note 2.q):				
Basic net income	¥ 120.1	¥ 124.5	\$ 1.04	
Diluted net income	120.1	124.5	1.04	
Cash dividends applicable to the period	48.0	48.0	0.42	

# Statement of Changes in Equity

		Millions of Yen								
				Capital Surplus (Note 7)			l Earnings ote 7)			
	Outstanding Number of Shares of Common Stock	Common Stock (Note 7)	Additional Paid-in Capital	Other Capital Surplus	Stock Acquisition Rights (Note 7)	Legal Reserve	Unappropriated	Unrealized Gain (Loss) on Available-for- Sale Securities	Treasury Stock	Total Equity
BALANCE, DECEMBER 31, 2019	28,073,039	¥ 5,190	¥ 6,416	¥ 13	¥ 11	¥ 1,297	¥ 100,779	¥ 850	¥ (1,431)	¥ 113,125
Net income							3,495			3,495
Cash dividends paid, ¥48.0 per share							(1,347)			(1,347)
Repurchase of treasury stock	(188)								(0)	(0)
Disposal of treasury stock	12,591			8					24	33
Net change in the year					(1)			(213)		(214)
BALANCE, DECEMBER 31, 2020	28,085,442	5,190	6,416	21	10	1,297	102,926	636	(1,407)	115,091
Net income							3,374			3,374
Cash dividends paid, ¥48.0 per share							(1,348)			(1,348)
Repurchase of treasury stock	(48)								(0)	(0)
Disposal of treasury stock	7,001			7					13	20
Net change in the year					(10)			(112)		(122)
BALANCE, DECEMBER 31, 2021	28,092,395	¥ 5,190	¥ 6,416	¥ 29		¥ 1,297	¥ 104,952	¥ 523	¥ (1,393)	¥ 117,015

	Thousands of U.S. Dollars (Note 1)								
	Capital Surplus (Note 7)			Retained Earnings (Note 7)					
	Common Stock (Note 7)	Additional Paid-in Capital	Other Capital Surplus	Stock Acquisition Rights (Note 7)	Legal Reserve	Unappropriated	Unrealized Gain (Loss) on Available-for- Sale Securities	Treasury Stock	Total Equity
BALANCE, DECEMBER 31, 2020	\$ 45,122	\$ 55,781	\$ 190	\$ 87	\$ 11,280	\$ 894,858	\$ 5,535	\$ (12,236)	\$ 1,000,620
Net income						29,338			29,338
Cash dividends paid, \$0.41 per share						(11,722)			(11,722)
Repurchase of treasury stock								(1)	(1)
Disposal of treasury stock			62					119	182
Net change in the year				(87)			(981)		(1,068)
BALANCE, DECEMBER 31, 2021	\$ 45,122	\$ 55,781	\$ 253		\$ 11,280	\$ 912,474	\$ 4,554	\$ (12,117)	\$ 1,017,349

## Statement of Cash Flows

	Millions	of Yen	Thousands of U.S. Dollars (Note 1)
	Year Ended December 31, 2021	Year Ended December 31, 2020	Year Ended December 31, 2021
OPERATING ACTIVITIES:			
Income before income taxes	¥ 4,767	¥ 4,225	\$ 41,448
Adjustments for:			
Income taxes paid	21	(9,410)	188
Depreciation and amortization	413	582	3,592
Business structure reform expenses	12	736	105
Payments for Business structure reform expenses	(11)	(501)	(98)
Changes in assets and liabilities:			
Increase (decrease) in accrued consumption taxes	330	(3,477)	2,874
Decrease (increase) in trade notes and accounts receivable	(1,345)	6,155	(11,700)
Decrease (increase) in inventories	(1,610)	360	(14,005)
Increase (decrease) in trade accounts payable	577	(629)	5,021
Other—net	(3,310)	(1,484)	(28,784)
Total adjustments	(4,923)	(7,668)	(42,806)
Net cash used in operating activities	(156)	(3,443)	(1,358)
INVESTING ACTIVITIES:  Purchases of marketable securities	(14,900)	(20,007)	(129.547)
	18,420	(29,007)	(129,547) 160,146
Proceeds from sale and redemption of marketable securities			
Purchases of property, plant and equipment  Proceeds from sale of property, plant and equipment	(150)	(293)	(1,312)
Purchases of investment securities	(9,376)	(9,837)	(81,517)
Proceeds from sale and redemption of investment securities	5,360	882	46,602
Payments for investments in capital	(200)	002	(1,738)
Proceeds from transfer of business	(200)	1,100	(1,/ 30)
Other—net	(651)	(118)	(5,661)
Net cash (used in) provided by investing activities	(1,498)	7,625	(13,028)
There easis (used in) provided by investing activities	(1,470)	7,027	(13,020)
FINANCING ACTIVITIES:			
Repurchase of treasury stock	0	0	(1)
Proceeds from exercise of stock option	(198)	8	(1,722)
Dividends paid		(1,347)	
Repayments of lease obligations	(1,348)	(85)	(11,722)
Net cash used in financing activities	(1,546)	(1,425)	(13,445)
NAME			/-
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	(3,201)	2,756	(27,832)
CASH AND CASH EQUIVALENTS, BEGINNING OF YEAR	61,576	58,819	535,350
CASH AND CASH EQUIVALENTS, END OF YEAR	¥ 58,374	¥ 61,576	\$ 507,518

## Notes to Financial Statements

#### BASIS OF PRESENTATION OF FINANCIAL STATEMENTS

The accompanying financial statements have been prepared in accordance with the provisions set forth in the Japanese Financial Instruments and Exchange Act and its related accounting regulations and in accordance with accounting principles generally accepted in Japan ("Japanese GAAP"), which are different in certain respects as to the application and disclosure requirements of International Financial Reporting Standards.

In preparing these financial statements, certain reclassifications and rearrangements have been made to the financial statements issued domestically in order to present them in a form which is more familiar to readers outside Japan. In addition, certain reclassifications have been made in the 2020 financial statements to conform to the classifications

used in 2021.

The financial statements are stated in Japanese yen, the currency of the country in which Torii Pharmaceutical Co., Ltd. (the "Company") is incorporated and operates. The translations of Japanese yen amounts into U.S. dollar amounts are included solely for the convenience of readers outside Japan and have been made at the rate of ¥115.02 to \$1, the approximate rate of exchange at December 31, 2021. Such translations should not be construed as representations that the Japanese ven amounts could be converted into U.S. dollars at that or any other rate.

Figures in the Company's financial statements and other items are generally rounded down.

#### **SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

- a. No consolidation—The Company has no subsidiaries as of December 31, 2021.
- b. Cash Equivalents—Cash equivalents are short-term investments that are readily convertible into cash and exposed to insignificant risk of changes in value.

Cash equivalents include time deposits, short-term investments, and deposits in the cash management system, all of which mature or become due within three months of the date of acquisition.

- c. Inventories—Inventories are stated at the lower of cost, determined by the weighted-average method, or net selling value.
- d. Marketable and Investment Securities—Marketable and investment securities are classified and accounted for, depending on management's intent as available-for-sale securities, which are reported at fair value, with unrealized gains and losses, net of applicable taxes, reported in a separate component of equity.

Nonmarketable available-for-sale securities are stated at cost determined by the moving-average method. For other-thantemporary declines in fair value, investment securities are reduced to net realizable value by a charge to income.

- e. Property, Plant and Equipment—Property, plant and equipment are stated at cost. Depreciation of property, plant and equipment of the Company is computed by the declining-balance method while the straight-line method is applied to buildings acquired on or after April 1, 1998, and building improvements and structures acquired on or after April 1, 2016. The range of useful lives is from 15 to 50 years for buildings and structures, and from 2 to 15 years for furniture and fixtures. Equipment held for lease is depreciated by the straight-line method over the respective lease periods.
- f. Software—Software is carried at cost less accumulated amortization, which is calculated by the straight-line method principally over 5 years.
- g. Retirement and Pension Plans—The Company has a contributory defined pension plan covering substantially all of its employees and an unfunded retirement lump-sum grants plan. The Company participates in a contributory multiemployer pension plan, the "Tokyo Pharmaceutical Company Pension Fund." For the contributory multiemployer pension plan, contributions to that plan are charged to income when paid. Plan assets contributed to this fund are not recorded in the balance sheet. The defined benefit

obligations are attributed to periods on a benefit formula basis. Actuarial gains and losses are amortized on a straight-line basis over 10 years within the average remaining service period. Past service costs are amortized on a straight-line basis over 5 years within the average remaining service period.

The liability for retirement benefits is accounted for based on defined benefit obligations and plan assets at the balance sheet date.

- h. Asset Retirement Obligations— An asset retirement obligation is recorded for a legal obligation imposed either by law or contract that results from the acquisition, construction, development and normal operation of a tangible fixed asset and is associated with the retirement of such tangible fixed asset. The asset retirement obligation is recognized as the sum of the discounted cash flows required for the future asset retirement and is recorded in the period in which the obligation is incurred if a reasonable estimate can be made. If a reasonable estimate of the asset retirement obligation cannot be made in the period the asset retirement obligation is incurred, the liability should be recognized when a reasonable estimate of the asset retirement obligation can be made. Upon initial recognition of a liability for an asset retirement obligation, an asset retirement cost is capitalized by increasing the carrying amount of the related fixed asset by the amount of the liability. The asset retirement cost is subsequently allocated to expense through depreciation over the remaining useful life of the asset. Over time, the liability is accreted to its present value each period. Any subsequent revisions to the timing or the amount of the original estimate of undiscounted cash flows are reflected as an adjustment to the carrying amount of the liability and the capitalized amount of the related asset retirement
- i. Stock Options—Compensation expense for employee stock options which were granted on and after May 1, 2006 are recognized based on the fair value at the date of grant and over the vesting period as consideration for receiving goods or services in accordance with ASBJ Statement No. 8, "Accounting Standard for Share-based Payment". Stock options granted to nonemployees are accounted for based on the fair value of either the stock option or the goods or services received. In the balance sheet, the stock option is presented as a stock acquisition right as a separate component of equity until exercised.

- **i. Research and Development Costs**—Research and development costs are charged to income as incurred.
- k. Leases— Finance lease transactions are capitalized to recognize lease assets and lease obligations in the balance sheet.

All other leases are accounted for as operating leases.

- 1. Bonuses to Directors and Audit & Supervisory Board Members— Bonuses to directors and Audit & Supervisory Board members are accrued at the year-end to which such bonuses are attributable.
- m. Income Taxes—The provision for income taxes is computed based on the pretax income included in the statement of income. The asset and liability approach is used to recognize deferred tax assets and liabilities for the expected future tax consequences of temporary differences between the carrying amounts and the tax bases of assets and liabilities. Deferred taxes are measured by applying currently enacted income tax rates to the temporary differences.
- n. Appropriations of Retained Earnings—Appropriations of retained earnings are reflected in the financial statements for the following year upon the shareholders' approval.
- o. Foreign Currency Transactions—All short-term and long-term monetary receivables and payables denominated in foreign currencies are translated into Japanese yen at the exchange rates at the balance sheet date. The foreign exchange gains and losses from translation are recognized in the statement of income to the extent that they are not hedged by forward exchange contracts.
- p. Derivatives and Hedging Activities—The Company uses derivative financial instruments to manage its exposures to fluctuations in foreign exchange. Foreign exchange forward contracts are utilized by the Company to reduce foreign currency exchange risks. The Company does not enter into derivatives for trading or speculative purposes.

Derivative financial instruments and foreign currency transactions are classified and accounted for as either assets or liabilities and measured at fair value.

Gains or losses on derivative transactions are recognized in the statement of income.

q. Per Share Information—Basic net income per share is computed by dividing net income available to common shareholders by the weighted-average number of common shares outstanding for the period, which was 28,090,290 shares and 28,079,831 shares for the years ended December 31, 2021 and 2020, respectively.

Diluted net income per share is not disclosed because there were no dilutive potential common shares that were outstanding during the year ended December 31, 2021.

Cash dividends per share presented in the accompanying statement of income are dividends applicable to the respective fiscal years, including dividends to be paid after the end of the year.

- r. Accounting Changes and Error Corrections—Under ASBJ Statement No. 24, "Accounting Standard for Accounting Changes and Error Corrections," and ASBJ Guidance No. 24, "Guidance on Accounting Standard for Accounting Changes and Error Corrections," accounting treatments are required as follows: (1) Changes in Accounting Policies—When a new accounting policy is applied following the revision of an accounting standard, the new policy is applied retrospectively unless the revised accounting standard includes specific transitional provisions, in which case the entity shall comply with the specific transitional provisions. (2) Changes in Presentation—When the presentation of financial statements is changed, prior-period financial statements are reclassified in accordance with the new presentation. (3) Changes in Accounting Estimates—A change in an accounting estimate is accounted for in the period of the change if the change affects that period only, and is accounted for prospectively if the change affects both the period of the change and future periods. (4) Corrections of Prior-Period Errors—When an error in prior-period financial statements is discovered, those statements are restated.
- s. New Accounting Pronouncements—"Accounting Standard for Revenue Recognition" (ASBJ Statement No. 29, March 31, 2020) and "Implementation Guidance on Accounting Standard for Revenue Recognition" (ASBJ Guidance No. 30, March 26, 2021)
  - (a) Overview

These are the comprehensive accounting standards for revenue recognition. Revenue is recognized based on the following five-step approach.

- Step 1: Identify the contract(s) with a customer
- Step 2: Identify the performance obligations in the contract
- Step 3: Determine the transaction price
- Step 4: Allocate the transaction price to the performance obligations in the contract
- Step 5: Recognize revenue when (or as) the entity satisfies a performance obligation
- (b) Scheduled Date of Adoption

The accounting standard and guidance are effective for annual periods beginning on or after April 1, 2021. Earlier application is permitted for annual periods beginning on or after April 1, 2018.

(c) Effect of Adoption

The Company expects to apply the accounting standard and guidance for annual periods beginning on or after January 1, 2022, and is in the process of measuring the effects of applying the accounting standard and guidance in future applicable periods.

#### SUMMARY OF SIGNIFICANT ACCOUNTING ESTIMATE

Evaluation of long-term prepaid expenses

#### (1) Carrying amounts

	Millions of Yen	Thousands of U.S. Dollars
	2021	2021
Long-term prepaid expenses	¥ 7,312	\$ 63,571

## (2) Information on the significant accounting estimate

We have recorded long-term prepaid expenses related to marketing rights that are deemed to be highly recoverable due to future earnings from expenditures related to in-licensing contracts, evenly expensed over the period of effect, and account for the large portion of long-term prepaid expenses of ¥7,312 million as of December 31, 2021.

If the actual earnings of each pharmaceutical product are continuously lower than plan, or if the future earnings based on the sales plan developed by the management will not be achieved, there is a possibility that there will be impairment indications of the marketing rights. If there are impairment indications and the total amount of expected future cash flows before discounts is less than the carrying amount of the marketing rights, an impairment loss is recognized.

## MARKETABLE AND INVESTMENT SECURITIES

Marketable and investment securities as of December 31, 2021 and 2020, consisted of the following:

	Millions of Yen		Thousands of U.S. Dollars
	December 31, 2021	December 31, 2020	December 31, 2021
Current:			
Government and corporate bonds	¥ 3,197	¥ 5,528	\$ 27,803
Trust fund investments and other	4,000		34,777
Total	¥ 7,198	¥ 5,528	\$ 62,580
Noncurrent:			
Equity securities	¥ 1,220	¥ 1,265	\$ 10,607
Government and corporate bonds	17,683	12,940	153,746
Trust fund investments and other	3,405	6,603	29,604
Total	¥ 22,309	¥ 20,810	\$ 193,957

The costs and aggregate fair values of marketable and investment securities at December 31, 2021 and 2020, were as follows:

			The costs and aggregate fair values of marketable and investment securities at December 31, 2021 and 2020, were as follows:			
Millions of Yen						
Cost	Unrealized Gains	Unrealized Losses	Fair Value			
¥ 357	¥ 752		¥ 1,110			
20,883	27	¥ 29	20,881			
7,405			7,405			
¥ 357	¥ 797		¥ 1,155			
18,485	32	¥ 47	18,469			
8,518	131		8,649			
	¥ 357 20,883 7,405 ¥ 357 18,485	Cost Unrealized Gains  # 357 # 752 20,883 27 7,405  # 357 # 797 18,485 32	Cost Unrealized Gains Unrealized Losses  # 357			

	Thousands of U.S. Dollars			
December 31, 2021	Cost	Unrealized Gains	Unrealized Losses	Fair Value
Available-for-sale:				
Equity securities	\$ 3,109	\$ 6,541		\$ 9,650
Debt securities	181,566	243	\$ 260	181,549
Other	64,380			64,381

Available-for-sale securities whose fair value was not readily determinable as of December 31, 2021 and 2020, were as follows:

	Carrying Amount		
	Millions of Yen		Thousands of U.S. Dollars
	December 31, 2021	December 31, 2020	December 31, 2021
Available-for-sale—Unlisted equity securities	¥ 110	¥ 110	\$ 956
Investment in limited partnership	¥ 886	¥ 954	\$ 7,710
Total	¥ 996	¥ 1,064	\$ 8,667

## **INVENTORIES**

Inventories at December 31, 2021 and 2020, consisted of the following:

	Millions of Yen		Thousands of U.S. Dollars
	December 31, 2021	December 31, 2020	December 31, 2021
Finished products and merchandise	¥ 5,542	¥ 4,285	\$ 48,185
Raw materials and supplies	3,221	2,866	28,006
Total	¥ 8,763	¥ 7,152	\$ 76,191

## RETIREMENT AND PENSION PLANS

Employees whose service with the Company is terminated are, under most circumstances, entitled to retirement and pension benefits determined by reference to basic rates of pay at the time of termination, length of service and conditions under which the termination occurs. If the termination is involuntary, caused by retirement at the mandatory retirement age or caused by death, the employee is entitled to greater

payments than in the case of voluntary termination. Additional retirement benefits which may be paid to employees upon retirement have not been included in the actuarial calculation of the projected benefit obligation. The net liabilities for retirement benefits at December 31, 2021 and 2020, consisted of the following:

## (1) The changes in defined benefit obligation for the years ended December 31, 2021 and 2020, were as follows:

Millions of Yen			Thousands of U.S. Dollars
	Year Ended December 31, 2021	Year Ended December 31, 2020	Year Ended December 31, 2021
Balance at beginning of period	¥ 6,226	¥ 6,760	\$ 54,130
Current service cost	302	325	2,629
Interest cost	37	38	324
Actuarial losses (gains)	(36)	104	(320)
Benefits paid	(243)	(331)	(2,120)
Decrease due to transfer of business		(671)	
Balance at end of period	¥ 6,285	¥ 6,226	\$ 54,643

## (2) The changes in plan assets for the years ended December 31, 2021 and 2020, were as follows:

	Millions of Yen		Thousands of U.S. Dollars
	Year Ended December 31, 2021	Year Ended December 31, 2020	Year Ended December 31, 2021
Balance at beginning of period	¥ 5,741	¥ 6,082	\$ 49,921
Expected return on plan assets	114	115	998
Actuarial gains	184	176	1,604
Contributions from the employer	217	224	1,891
Benefits paid	(229)	(286)	(1,998)
Decrease due to transfer of business		(571)	
Balance at end of period	¥ 6,029	¥ 5,741	\$ 52,417

## (3) Reconciliation between the liability recorded in the balance sheet and the balances of defined benefit obligation and plan assets was as follows:

	Millions of Yen		Thousands of U.S. Dollars
	December 31, 2021	December 31, 2020	December 31, 2021
Funded defined benefit obligation	¥ 5,602	¥ 5,545	\$ 48,712
Plan assets	(6,029)	(5,741)	(52,417)
	(426)	(196)	(3,704)
Unfunded defined benefit obligation	682	680	5,931
Unrecognized actuarial losses	581	464	5,053
Net liability arising from defined benefit obligation	¥ 837	¥ 948	\$ 7,280

Millions of Yen		Thousands of U.S. Dollars	
	December 31, 2021	December 31, 2020	December 31, 2021
Liability for retirement benefits	¥ 837	¥ 948	\$ 7,280
Net liability arising from defined benefit obligation	¥ 837	¥ 948	\$ 7,280

#### (4) The components of net periodic benefit costs for the years ended December 31, 2021 and 2020, were as follows:

	Million	Thousands of U.S. Dollars	
	Year Ended December 31, 2021	Year Ended December 31, 2020	Year Ended December 31, 2021
Service cost	¥ 302	¥ 325	\$ 2,629
Interest cost	37	38	324
Expected return on plan assets	(114)	(115)	(998)
Recognized actuarial (gains) losses	(104)	(71)	(908)
Net periodic benefit costs	¥ 120	¥ 177	\$ 1,047

#### (5) Plan assets

## a. Components of plan assets

Plan assets consisted of the following:

	December 31, 2021	December 31, 2020
Debt investments	47%	42%
Equity investments	25	28
General account of life insurance companies	8	9
Others	20	21
Total	100%	100%

Notes: "Others" mainly includes insurance-linked products and hedge funds.

## b. Method of determining the expected rate of return on plan assets

The expected rate of return on plan assets is determined considering the long-term rates of return which are expected currently and in the future from the various components of the plan assets.

#### (6) Assumptions used for the years ended December 31, 2021 and 2020, were set forth as follows:

	Year Ended	Year Ended
	December 31,	December 31,
	2021	2020
Discount rate	0.6%	0.6%
Expected rate of return on plan assets	2.0	2.0

#### (7) Multiemployer pension plan

Contributions to the multiemployer pension plan of ¥54 million (\$475 thousand) and ¥59 million are disclosed in cost of sales and selling, general and administrative expenses for the years ended December 31, 2021 and 2020 respectively, for which plan assets could not be allocated to each participating employer.

The funded status of the multiemployer pension plan at December 31, 2021 (based on information available as of March 31, 2021) and December 31, 2020 (based on information available as of March 31, 2020) to which contributions were recorded as net periodic retirement benefit costs, was as follows:

	Millions of	fYen	Thousands of U.S. Dollars
	March 2021	31 2020	March 31, 2021
Fair value of plan assets	¥ 166,870	¥ 151,134	\$ 1,450,799
Sum of actuarial liabilities of pension plan and minimum actuarial reserve	150,293	150,361	1,306,675
Difference	¥ 16,577	¥ 773	\$ 144

The Company's contribution percentage for the multiemployer pension plan at December 31, 2021 and 2020, was as follows:

	December 31, 2021	December 31, 2020
Contribution percentage	0.8%	0.8%

#### Notes (March 31, 2021):

- 1. The difference mainly resulted from prior service cost of \(\frac{\psi}{8},572\) million (\(\frac{\psi}{4},526\)) thousand), surplus brought forward of ¥13,336 million (\$115,945 thousand)and special reserve fund of ¥11,813 million (\$102,703 thousand).
- 2. Prior service cost is the present value of the amount of special contributions and the method of amortization is principal and interest equal repayment. The ratio of employer contribution is 0.7%. The remaining term of amortization is 3 years and 5 months as of March 31, 2021.

## Notes (March 31, 2020):

- 1. The difference mainly resulted from prior service cost of ¥(11,040) million, deficiency brought forward of ¥(7,003) million (\$(67,663) thousand) and special reserve fund of ¥18,816 million.
- 2. Prior service cost is the present value of the amount of special contributions and the method of amortization is equal to the payment terms. The ratio of employer contribution is 0.7%. The remaining term of amortization is 4 years and 5 months as of March 31, 2020.

## **EQUITY**

Japanese companies are subject to the Companies Act of Japan (the "Companies Act"). The significant provisions in the Companies Act that affect financial and accounting matters are summarized below:

#### a. Dividends

Under the Companies Act, companies can pay dividends at any time during the fiscal year in addition to the year-end dividend upon resolution at the shareholders' meeting. Additionally, for companies that meet certain criteria including (1) having a Board of Directors, (2) having independent auditors, (3) having an Audit & Supervisory Board, and (4) the term of service of the directors being prescribed as one year rather than the normal two-year term by its articles of incorporation, the Board of Directors may declare dividends (except for dividends-in-kind) at any time during the fiscal year if the Company has prescribed so in its articles of incorporation. However, the Company does not meet all the above criteria.

Semiannual interim dividends may also be paid once a year upon resolution by the Board of Directors if the articles of incorporation of the company so stipulate. The Companies Act provides certain limitations on the amounts available for dividends or the purchase of treasury stock. The limitation is defined as the amount available for distribution to the shareholders, but the amount of net assets after dividends must be maintained at no less than \(\frac{1}{2}\)3 million.

## b. Increases/Decreases and Transfer of Common Stock, Reserve and Surplus

The Companies Act requires that an amount equal to 10% of dividends must be appropriated as a legal reserve (a component of retained earnings) or as additional paid-in capital (a component of capital surplus), depending on the equity account charged upon the payment of such dividends, until the aggregate amount of legal reserve and additional paid-in capital equals 25% of the common stock. Under the Companies Act, the total amount of additional paid-in capital and legal reserve may be reversed without limitation. The Companies Act also provides that common stock, legal reserve, additional paid-in capital, other capital surplus and retained earnings can be transferred among the accounts within equity under certain conditions upon resolution of the shareholders.

#### c. Treasury Stock and Treasury Stock Acquisition Rights

The Companies Act also provides for companies to purchase treasury stock and dispose of such treasury stock by resolution of the Board of Directors. The amount of treasury stock purchased cannot exceed the amount available for distribution to the shareholders which is determined by a specific formula.

Under the Companies Act, stock acquisition rights are presented as a separate component of equity. The Companies Act also provides that companies can purchase both treasury stock acquisition rights and treasury stock. Such treasury stock acquisition rights are presented as a separate component of equity or deducted directly from stock acquisition rights.

## 8

## **STOCK OPTIONS**

The stock options outstanding as of December 31, 2021, are as follows:

Stock Option	Persons	Number of	Date of	Exercise	Exercise
	Granted	Options Granted	Grant	Price	Period
2016 Stock Option	6 Directors 6 Executive Vice Presidents	28,000 shares	2016.4.8	¥ 2,736 (\$ 23)	From April 9, 2018 to April 8, 2021

The stock option activity is as follows:

	2016 Stock Option
Year Ended December 31, 2020	(Shares)
Non-vested	
December 31, 2019—Outstanding	
Granted	
Canceled	
Vested	
December 31, 2020—Outstanding	
Vested	
December 31, 2019—Outstanding	26,400
Vested	
Exercised	
Canceled	
December 31, 2020—Outstanding	26,400
Year Ended December 31, 2021 Non-vested	
December 31, 2020—Outstanding	
Granted	
Canceled	
Vested	
December 31, 2021—Outstanding	
Vested	
December 31, 2020—Outstanding	23,400
Vested	
Exercised	
Canceled	23,400
December 31, 2021—Outstanding	
Exercise price	¥ 2,736 (\$ 23)
Average stock price at exercise	
Fair value price at grant date	¥ 427.70 (\$ 3.72)

## 9

## **INCOME TAXES**

The Company is subject to Japanese national and local income taxes, which, in the aggregate, resulted in a normal effective statutory tax rate of approximately 30.6% and 30.6% for the years ended December 31, 2021 and 2020, respectively.

The tax effects of significant temporary differences, which resulted in deferred tax assets and liabilities at December 31, 2021 and 2020, are as follows:

	Million	Millions of Yen		
	December 31, 2021	December 31, 2020	December 31, 2021	
Deferred tax assets:				
Accrued enterprise taxes	¥ 94	¥ 18	\$ 817	
Liabilities for retirement benefits	256	290	2,227	
Accrued expenses	47	41	417	
Prepayment of research and development costs	45	48	396	
Accrued bonuses to employees	120	119	1,050	
Loss on valuation of inventories	15	42	137	
Other	311	351	2,711	
Less valuation allowance	(29)	(43)	(258)	
Total	862	868	7,499	
Deferred tax liabilities:				
Unrealized gain on available-for-sale securities	226	276	1,971	
Other	(5)	3	(50)	
Total	220	280	1,920	
Net deferred tax assets	¥ 641	¥ 587	\$ 5,579	

A reconciliation between the normal effective statutory tax rates and the actual effective tax rates as reflected in the accompanying statement of income for the year ended December 31, 2021, with the corresponding figures for 2020, is as follows:

	Year Ended	Year Ended
	December 31,	December 31,
	2021	2020
Normal effective statutory tax rate	30.6%	30.6%
Expenses not deductible for income tax purposes	0.2	0.8
Dividend income deductible for income tax purposes	(0.0)	(0.0)
Per capita levy	0.7	0.9
Tax credits	(0.9)	
Increase in valuation allowance	(0.3)	(15.3)
Other—net	(1.1)	0.3
Actual effective tax rate	29.2%	17.3%

## 10

#### RESEARCH AND DEVELOPMENT COSTS

Research and development costs charged to income were ¥832 million (\$7,238 thousand) and ¥596 million for the years ended December 31, 2021 and 2020, respectively.

## 11

#### **LEASES**

The Company leases certain office space and other assets under operating leases.

Total rental expenses including lease payments under finance leases for the years ended December 31, 2021 and 2020, were ¥491 million (\$4,277 thousand) and ¥475 million, respectively.

The minimum rental commitments under noncancelable operating leases were as follows:

	Millions of Yen
	2021
	Operating Leases
Due within one year	¥ 29
Due after one year	29
Total	¥ 58

Thousands of U.S. Dollars	
2021	
Operating Leases	
	\$ 256
	254
	\$ 511

## 12

## FINANCIAL INSTRUMENTS AND RELATED DISCLOSURES

## (1) Policy for Financial Instruments

To provide for a new business investment, the Company invests surplus funds in financial instruments, which are selected primarily for liquidity and security. Derivatives are used, not for speculative purposes, but to manage exposure to financial risks as described in (2) below.

## (2) Nature of Financial Instruments and Related Risks, and Risk Management Systems

Receivables, such as trade notes and trade accounts, are exposed to customer credit risk. The Company manages due dates and outstanding balances for individual customers in accordance with its credit management rules. The Company has also established a system to monitor the credit status of major customers on a biannual basis.

Marketable and investment securities consist mainly of bonds, held with the aim of investing surplus funds and shares in companies with which the Company has business relationships. These bonds and shares are exposed to the credit risk of the issuers and to the risk of market price fluctuation.

Most trade accounts and accrued payments, which are operating liabilities, have due dates within one year. Some of these items are denominated in foreign currencies and are therefore exposed to the risk of exchange rate fluctuations. Derivatives are forward foreign currency contracts, which are used to manage exposure to financial risks from changes in foreign currency exchange rates of payables.

## (3) Fair Values of Financial Instruments

Fair values of financial instruments are based on quoted prices in active markets. If a quoted price is not available, another rational valuation technique is used instead.

## (a) Fair values of financial instruments

	Millions of Yen		
December 31, 2021	Carrying Amount	Fair Value	Unrealized Gain/Loss
Cash and cash equivalents	¥ 58,374	¥ 58,374	
Receivables:			
Trade accounts	20,302	20,302	
Parent	1,754	1,754	
Marketable and investment securities—Available-for-sale securities	29,397	29,397	
Total	¥ 109,828	¥ 109,828	
Payables:			
Trade accounts	¥ 4,084	¥ 4,084	
Parent	1,761	1,761	
Other	3,275	3,275	
Income taxes payable	1,536	1,536	
Total	¥ 10,657	¥ 10,657	
December 31, 2020			
Cash and cash equivalents	¥ 61,576	¥ 61,576	
Receivables:			
Trade accounts	18,949	18,949	
Parent	119	119	
Marketable and investment securities—Available-for-sale securities	29,228	29,228	
Total	¥ 109,873	¥ 109,873	
Payables:			
Trade accounts	¥ 3,929	¥ 3,929	
Parent	1,274	1,274	
Other	3,026	3,026	
Income taxes payable	41	41	
Total	¥ 8,271	¥ 8,271	

	Thousands of U.S. Dollars		
December 31, 2021	Carrying Amount	Fair Value	Unrealized Gain/Loss
Cash and cash equivalents	\$ 507,518	\$ 507,518	
Receivables:			
Trade accounts	176,509	176,509	
Parent	15,257	15,257	
Marketable and investment securities—Available-for-sale securities	255,582	255,582	
Total	\$ 954,867	\$ 954,867	
Payables:			
Trade accounts	\$ 35,510	\$ 35,510	
Parent	15,313	15,313	
Other	28,475	28,475	
Income taxes payable	13,362	13,362	
Total	\$ 92,661	\$ 92,661	

## Cash and Cash Equivalents, Receivables, Payables, and Income Taxes Payable

The carrying values of cash and cash equivalents, receivables, payables, and income taxes payable approximate fair value because of their short maturities.

#### Marketable and Investment Securities

The fair values of marketable and investment securities are measured at the quoted market price of the stock exchange for the equity instruments, and at the quoted price obtained from the financial institution for certain debt instruments. The information on the fair values of marketable and investment securities by classification is included in Note 3.

## (b) Financial instruments whose fair value cannot be reliably determined

	Carrying Amount		
	Millions	Thousands of U.S. Dollars	
	December 31, December 31, 2021 2020		December 31, 2021
Unlisted shares	¥ 110	¥ 110	\$ 956
Investment in limited partnership	886	954	7,710
Total	¥ 996	¥ 1,064	\$ 8,667

There are no market prices for these items and it is likely that the cost of estimating future cash flows would be excessive.

## (4) Maturity Analysis for Financial Assets and Securities with Contractual Maturities

	Millions of Yen		
December 31, 2021	Due in 1 Year or Less	Due after 1 Year through 5 Years	Due after 5 Years through 10 Years
Cash and cash equivalents	¥ 58,374		
Receivables:			
Trade accounts	20,302		
Parent	1,754		
Marketable and investment securities—Available-for-sale securities with contractual maturities	7,198	¥ 11,067	¥ 2,301
Total	¥ 87,629	¥ 11,067	¥ 2,301

	Millions of Yen		
December 31, 2020	Due in 1 Year or Less	Due after 1 Year through 5 Years	Due after 5 Years through 10 Years
Cash and cash equivalents	¥ 61,575		
Receivables:			
Trade accounts	18,949		
Parent	119		
Marketable and investment securities—Available-for-sale securities with contractual maturities	5,528	¥ 8,218	¥ 4,932
Total	¥ 86,173	¥ 8,218	¥ 4,932

	Thousands of U.S. Dollars		
December 31, 2021	Due in 1 Year or Less	Due after 1 Year through 5 Years	Due after 5 Years through 10 Years
Cash and cash equivalents	\$ 507,517		
Receivables:			
Trade accounts	176,509		
Parent	15,257		
Marketable and investment securities—Available-for-sale securities with contractual maturities	62,580	\$ 96,218	\$ 20,012
Total	\$ 761,865	\$ 96,218	\$ 20,012

#### 13 RELATED PARTY TRANSACTIONS

Transactions of the Company with the parent company for the years ended December 31, 2021 and 2020, were as follows:

	Million	Millions of Yen		
	Year Ended December 31, 2021	Year Ended December 31, 2020	Year Ended December 31, 2021	
Purchases	¥ 6,059	¥ 3,318	\$ 52,684	
Forward exchange contracts	8,192	3,267	71,225	

The balances due to or from the parent company at December 31, 2021 and 2020, were as follows:

	Millions of Yen		Thousands of U.S. Dollars
	December 31, 2021	December 31, 2020	December 31, 2021
Deposits included in cash and cash equivalents	¥ 23,362	¥ 27,859	\$ 203,114
Trade accounts payable	1,708	1,213	14,855

#### 14 **BUSINESS STRUCTURE REFORM EXPENSES**

Business structure reform expenses are the amount of labor cost-related losses related to the transfer of Sakura Plant in the previous fiscal year.

## 15

## **SEGMENT INFORMATION**

Under ASBJ Statement No. 17, "Accounting Standard for Segment Information Disclosures," and ASBJ Guidance No. 20, "Guidance on Accounting Standard for Segment Information Disclosures," an entity is required to report financial and descriptive information about its reportable segments. Reportable segments are operating segments or aggregations of operating segments that meet specified criteria. Operating segments are components of an entity about which separate financial information is available and such information is evaluated regularly by the chief operating

decision-maker in deciding how to allocate resources and in assessing performance. Generally, segment information is required to be reported on the same basis as is used internally for evaluating operating segment performance and deciding how to allocate resources to operating segments.

Information relating to business segments is omitted as the Company operated solely in the pharmaceutical business for the years ended December 31, 2021 and 2020.

Sales to major customers were as follows:

	Millions of Yen		Thousands of U.S. Dollars
Name of Customer	Year Ended December 31, 2021	Year Ended December 31, 2020	Year Ended December 31, 2021
Alfresa Corporation	¥ 10,678	¥ 9,398	\$ 92,838
Mediceo Corporation	10,467	9,041	91,003
Suzuken Co., Ltd.	10,101	8,564	87,821
Toho Pharmaceutical Co., Ltd.	5,257	4,645	45,706

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#### INDEPENDENT AUDITOR'S REPORT

To the Board of Directors of Torii Pharmaceutical Co., Ltd.:

#### Opinion

We have audited the financial statements of Torii Pharmaceutical Co., Ltd. (the "Company"), which comprise the balance sheet as of December 31, 2021, and the statement of income, statement of changes in equity and statement of cash flows for the year then ended, and notes to the financial statements, including a summary of significant accounting policies, all expressed in Japanese yen.

In our opinion, the accompanying financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2021, and its financial performance and its cash flows for the year then ended in accordance with accounting principles generally accepted in Japan.

#### Convenience Translation

Our audit also comprehended the translation of Japanese yen amounts into U.S. dollar amounts and, in our opinion, such translation has been made in accordance with the basis stated in Note 1 to the financial statements. Such U.S. dollar amounts are presented solely for the convenience of readers outside Japan.

## **Basis for Opinion**

We conducted our audit in accordance with auditing standards generally accepted in Japan. Our responsibilities under those standards are further described in the Auditor's Responsibilities for the Audit of the Financial Statements section of our report. We are independent of the Company in accordance with the provisions of the Code of Professional Ethics in Japan, and we have fulfilled our other ethical responsibilities as auditors. We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

## **Key Audit Matters**

Key audit matters are those matters that, in our professional judgment, were of most significance in our audit of the financial statements of the current period. These matters were addressed in the context of our audit of the financial statements as a whole, and in forming our opinion thereon, and we do not provide a separate opinion on these matters.

#### Initial Acquisition of Marketing Rights

#### Key Audit Matter Description

The Company has recorded long-term prepaid expenses related to marketing rights that are deemed to be highly recoverable due to future earnings from expenditures related to in-licensing contracts, and account for the large portion of long-term prepaid expenses of ¥7,312 million as of December 31, 2021.

In March 2021, the Company has entered into a License Agreement with Verrica Pharmaceuticals Inc. in the United States with respect to the exclusive development and commercialization of skin disease treatment drug VP-102 in Japan. The Company has recorded ¥1,211 million in long-term prepaid expenses as marketing rights for related expenditures.

For marketing rights related to VP-102 that were newly recorded on the balance sheet during the current fiscal year, the management evaluates the profitability of the pharmaceuticals based on the business plan formulated and the assumption that it is recoverable from future earnings.

Significant assumptions used in management's assessment of the profitability are future marketability. drug price, the expected number of the patients and the market share. Management determined these assumptions based on external data.

As described above, estimates of significant assumptions, on which assessments of VP-102 profitability are based, depend on forecasting future earnings and involve judgments made by management.

Therefore as these management's judgments have a significant impact on the recoverability of initial acquisition marketing rights, we have determined the initial acquisition of marketing rights to be a key audit matter.

How the Key Audit Matter Was Addressed in the Audit

Our audit procedures on the recoverability of initial acquisition of marketing rights related to VP-102 included the followings. among others:

- · We tested the design and operating effectiveness of internal controls over the process to ensure the business plan based on the assessments of VP- 102 profitability is appropriately prepared.
- We inspected in-licensing contracts of VP-102 to obtain an understanding of the transactions as well as the rights and obligations of the Company involved in the contracts.
- · We evaluated the reasonableness of the future marketability, the drug price, the expected number of the patients and the market share, which are significant assumptions in the assessment of VP-102 profitability, by making inquiries of the management about their estimation method and rationale. We also tested the consistency with external data used in the management estimate.
- We considered whether an indication of management bias existed when management estimated future revenues from VP-102, by comparing management's projected revenues for other previous in-licensing contracts with actual results.

#### Determination of Indicators of Impairment of Marketing Rights

#### Key Audit Matter Description

The Company has recorded long-term prepaid expenses related to marketing rights that are deemed to be highly recoverable due to future earnings from expenditures related to in-licensing contracts, and account for the large portion of long-term prepaid expenses of ¥7,312 million as of December 31, 2021.

As described in notes to the financial statements "SUMMARY OF SIGNIFICANT ACCOUNTING ESTIMATE," "Evaluation of long-term prepaid expenses," the Company has recorded long-term prepaid expenses related to marketing rights that is expected to generate future revenues, and assessed for indications of impairment for each of the marketing rights for its pharmaceutical products. The Company assessed for impairment indicators by using the earning forecast based on the sales plan developed by the management.

If the actual earnings of each pharmaceutical product are continuously negative, or if the future earning forecast based on the sales plan developed by the management will not be achieved, there is a possibility that there will be impairment indications of the marketing rights. If there are impairment indications and the total amount of expected future cash flows before discounts is less than the carrying amount of the marketing rights, an impairment loss is recognized.

As described above, the earning forecast based on the sales plan depends on future forecast and involves management judgments.

Since these management's judgments have a significant impact on the determination of impairment indications of marketing rights, we have identified the determination of indicators of impairment of marketing rights to be a key audit matter.

How the Key Audit Matter Was Addressed in the Audit

Our audit procedures on the determination of indicators of impairment of marketing rights included the following, among others:

- · We tested the design and operating effectiveness of internal controls over the process to ensure the material for the determination of impairment indication is appropriately prepared and reviewed.
- We made inquiries of the management and read the minutes to evaluate that there are no changes that could have a significant impact on the future earning forecast based on the sales plan developed by the management.
- · We obtained management analysis for the impairment indication testing and evaluated whether the actual earnings of each pharmaceutical products continued to be negative.
- · We considered whether an indication of management bias existed in management's forecast of the earnings of each pharmaceutical product by comparing the earning forecast based on the sales plan developed by management with actual results.

## Responsibilities of Management and Audit & Supervisory Board Members and the Audit & Supervisory Board for the Financial Statements

Management is responsible for the preparation and fair presentation of the financial statements in accordance with accounting principles generally accepted in Japan, and for such internal control as management determines is necessary to enable the preparation of financial statements that are free from material misstatement, whether due to fraud or error.

In preparing the financial statements, management is responsible for assessing the Company's ability to continue as a going concern, disclosing, as applicable, matters related to going concern in accordance with accounting principles generally accepted in Japan and using the going concern basis of accounting unless management either intends to liquidate the Company or to cease operations, or has no realistic alternative but to do so.

Audit & Supervisory Board members and the Audit & Supervisory Board are responsible for overseeing the Directors' execution of duties relating to the design and operating effectiveness of the controls over the Company's financial reporting process.

#### Auditor's Responsibilities for the Audit of the Financial Statements

Our objectives are to obtain reasonable assurance about whether the financial statements as a whole are free from material misstatement, whether due to fraud or error, and to issue an auditor's report that includes our opinion. Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with auditing standards generally accepted in Japan will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these financial statements.

As part of an audit in accordance with auditing standards generally accepted in Japan, we exercise professional judgment and maintain professional skepticism throughout the audit, We also:

- Identify and assess the risks of material misstatement of the financial statements, whether due to fraud or error, design and perform audit procedures responsive to those risks. The procedures selected depend on the auditor's judgment. In addition, we obtain audit evidence that is sufficient and appropriate to provide a basis for our opinion. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control.
- · Obtain, when performing risk assessment procedures, an understanding of internal control relevant to the audit in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control.
- Evaluate the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures made by management.
- Conclude on the appropriateness of management's use of the going concern basis of accounting and. based on the audit evidence obtained, whether a material uncertainty exists related to events or conditions that may cast significant doubt on the Company's ability to continue as a going concern. If we conclude that a material uncertainty exists, we are required to draw attention in our auditor's report to the related disclosures in the financial statements or, if such disclosures are inadequate, to modify our opinion. Our conclusions are based on the audit evidence obtained up to the date of our auditor's report. However, future events or conditions may cause the Company to cease to continue as a going concern.
- Evaluate whether the overall presentation and disclosures of the financial statements are in accordance with accounting principles generally accepted in Japan, as well as the overall presentation, structure and content of the financial statements, including the disclosures, and whether the financial statements represent the underlying transactions and events in a manner that achieves fair presentation.

We communicate with Audit & Supervisory Board members and the Audit & Supervisory Board regarding, among other matters, the planned scope and timing of the audit and significant audit findings, including any significant deficiencies in internal control that we identify during our audit.

We also provide Audit & Supervisory Board members and the Audit & Supervisory Board with a statement that we have complied with relevant ethical requirements regarding independence, and communicate with them all relationships and other matters that may reasonably be thought to bear on our independence, and where applicable, related safeguards.

From the matters communicated with Audit & Supervisory Board members and the Audit & Supervisory Board, we determine those matters that were of most significance in the audit of the financial statements of the current period and are therefore the key audit matters. We describe these matters in our auditor's report unless law or regulation precludes public disclosure about the matter or when, in extremely rare circumstances, we determine that a matter should not be communicated in our report because the adverse consequences of doing so would reasonably be expected to outweigh the public interest benefits of such communication.

## Interest Required to Be Disclosed by the Certified Public Accountants Act of Japan

Our firm and its designated engagement partners do not have any interest in the Company which is required to be disclosed pursuant to the provisions of the Certified Public Accountants Act of Japan.

Doloitte Touche Tohmatsu LLC

March 17, 2022

## Corporate Information

## Corporate Overview

Corporate name Torii Pharmaceutical Co., Ltd.

Established November 1, 1921 Paid-in capital ¥5,190 million

**Business line** Manufacturing and marketing of pharmaceutical

products

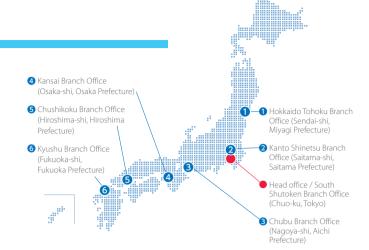
Number of employees 560 (as of December 31, 2021)

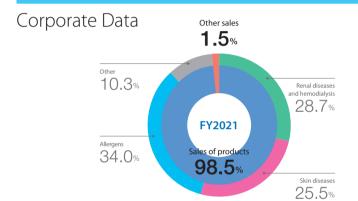
Stock exchange listing The Prime Market of the Tokyo Stock Exchange

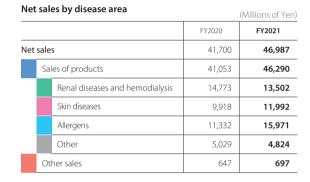
(Securities code: 4551)

Head office 4-1, Nihonbashi-Honcho 3-chome, Chuo-ku,

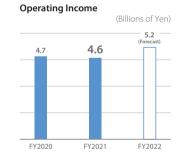
Tokyo 103-8439, Japan Telephone: +81-3-3231-6811

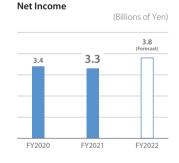












## Mainstay Products (as of December 31, 2021)

Riona Tablets Therapeutic agent for hyperphosphatemia/ Therapeutic drug for iron deficiency anemia (IDA)



Riona is a medication that treats hyperphosphatemia in patients with chronic kidney disease, including hemodialysis, peritoneal dialysis, and non-dialysis chronic kidney disease patients. Approval for an additional indication of iron deficiency aner (IDA) was received in March 2021.

ANTEBATE Topical corticosteroid



ANTEBETE is a treatment that improves the symptoms in patients with skin diseases, such as atopic dermatitis and contact dermatitis, by suppressing inflammation

## REMITCH Oral antipruritic agent



REMITCH is a treatment for pruritus in patients on dialysis and with chronic liver disease for which conventional antipruritic medications are ineffective.

CEDARCURE Japanese Cedar Pollen Sublingual Tablets Japanese cedar pollinosis (allergen immunotherapy)



CEDARCURE is a sublingual CEDARCURE IS a Sublingual allergen immunotherapy drug for Japanese cedar pollinosis. This fast-dissolving sublingual tablet was the first of its kind available in Japan for adult and pediatric

## CORECTIM Topical Janus kinase (JAK) inhibitor



CORECTIM® Ointment is the world's first topical JAK inhibitor for treatment of atopic dermatitis that suppresses the overactivation of immune responses by inhibiting the action of JAKs, which play key roles in immune activation signaling in cells.

MITICURE House Dust Mite Sublingual Tablets House dust mite allergy (allergen immunotherapy)



MITICURE is an allergen immuno-therapy tablet for house dust mite-induced allergic rhinitis. Additional dosage and adminis-tration of this drug for pediatric indication was approved in February 2018.



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