



# Annual Report 2019

*For the year ended  
December 31,  
2019*



TORII PHARMACEUTICAL CO., LTD.

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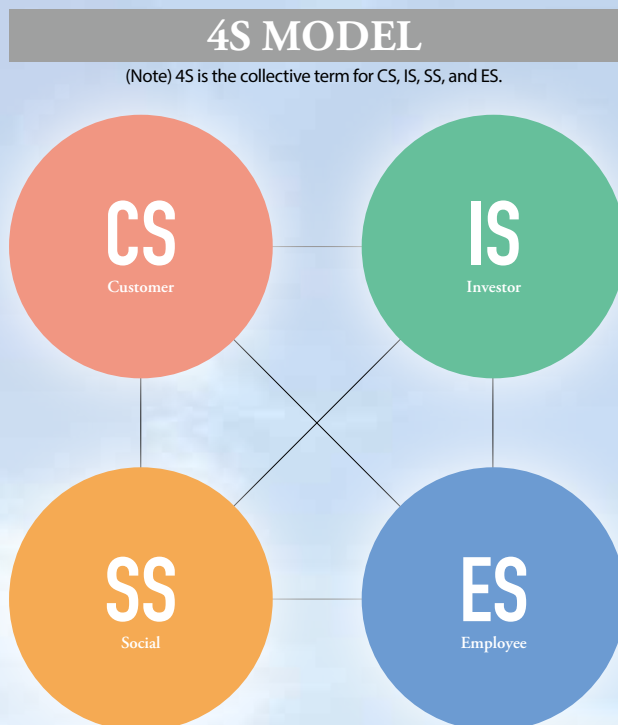
# Corporate Mission / The Torii Action Declaration

## The Corporate Mission of Torii

Torii Pharmaceutical Co., Ltd. (hereinafter “Torii”) aims to contribute to the improvement of human health and to fulfill its responsibilities to customers, shareholders, society and employees, by supplying world-class pharmaceutical products.

We are dedicated to enhancing the satisfaction of customers, shareholders, society and employees through the fulfillment of our responsibilities with regard to each.

We will achieve this through the reinvestment of revenue generated from our diligent corporate activities.



### **CS** *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.

### **SS** *Social Satisfaction* Our Responsibility to Society

We maintain a high ethical standard regarding our corporate social responsibility through business activities that reflect the needs of society.

### **IS** *Investor Satisfaction* Our Responsibility to Shareholders

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

### **ES** *Employee Satisfaction* Our Responsibility to Employees

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.

## The Torii Action Declaration

We gain the trust of our customers through thinking flexibly,  
working cooperatively and acting quickly.

# Message from the President

We will continue to make concerted efforts throughout the Company to achieve sustainable business growth and boost corporate value over the medium to long term, based on the corporate mission of “contributing to the improvement of human health and to fulfill its responsibilities to customers, shareholders, society and employees, by supplying world-class pharmaceutical products.”

We look forward to your continued support and cooperation.

## Goichi Matsuda

Representative Director,  
President and Chief Executive Officer



### ■ At the End of Fiscal 2019

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 research and development costs, intensifying international competition and other factors. In the Japanese market, in particular, with the promotion of health care system reforms, there has been an urgent need to curb healthcare expenditures, such as through the drastic reform of the drug pricing system and encouragement of greater use of generic drugs. Moreover, the termination of the exclusive rights to market six anti-HIV drugs in Japan (Viread Tablets, Emtriva Capsules, Truvada Combination Tablets, Stribild Combination Tablets, Genvoya Combination Tablets, and Descovy Combination Tablets) had a strong financial impact on Torii.

With a view to such an increasingly challenging business environment, Torii established the Medium-Term Management Plan 2021 on February 6, 2019. In accordance with the plan, Torii implemented three measures: ❶ business structure reform, ❷ growth strategy, and ❸ maintaining the trust of stakeholders.

As a result, with regard to financial results for fiscal 2019, Torii recorded positive figures for both operating income and ordinary income, partly because sales of “CEDARCURE® Japanese Cedar Pollen Sublingual Tablets,” an Allergen Immunotherapy Tablet for Japanese Cedar Pollinosis, exceeded the initial forecast.

As announced on February 6, 2020, Torii achieved in fiscal 2019 the target set by the Medium-Term Management Plan 2021, which was “to turn operating income\* positive in fiscal 2022,” thus meeting the goal earlier than planned. In view of these results, Torii has set a new target, which is “to keep operating income\* positive and to increase profit throughout the period covered by the Medium-Term Management Plan 2021.” And Torii will continue to promote vigorous new business investments to ensure future profit growth.

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

# Progress of the Medium-Term Management Plan 2021 and Revision of the Targets

Torii is implementing its Medium-Term Management Plan 2021 (announced on February 6, 2019) starting from fiscal 2019. Torii hereby announces that it has decided to revise the targets of the plan in view of progress thus far, as stated below.

## Progress of the Medium-Term Management Plan 2021

(As of March 26, 2020)

Torii established the Medium-Term Management Plan 2021, covering the three-year period from fiscal 2019, with the aim of turning operating income\* positive in fiscal 2022 and continuously generating profit thereafter. In accordance with the plan, Torii implemented three measures: ① business structure reform, ② growth strategy, and ③ maintaining the trust of stakeholders.

The progress of the major measures listed as priority issues is as follows.

### ① Business structure reform

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

### Progress

- Introduction of a special program supporting employees who wish to retire voluntarily and embark on a new career
- Reorganization (consolidation and elimination of branches, integration of R&D functions into Japan Tobacco Inc. (JT), and reorganization of the head office)
- Transfer of production of long-term listed drugs (FUTHAN (protease inhibitor), URINORM(uricosuric agent)) to other companies
- Introduction of a new sales support system and tablet terminals
- Decision on transfer of the Sakura Plant

### 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

### Progress

#### Development activities

- JT to receive a manufacturing and marketing approval for CORECTIM® Ointment 0.5% (JTE-052) for the treatment of atopic dermatitis in Japan (January 2020)
- Top-line results of JTE-052 Ointment, JAK inhibitor, phase 3 clinical study in pediatric patients with atopic dermatitis (comparative study) in Japan (April 2019)
- Top-line results of phase 3 clinical study (comparative study) of Riona® (JTT-751) in adult patients with iron deficiency anemia in Japan (July 2019)
- JT to file a New Drug Application for a manufacturing and marketing approval for enarodustat (JTZ-951), a hypoxia inducible factor prolyl hydroxylase (HIF-PH) inhibitor, for the treatment of anemia associated with chronic kidney disease (CKD) in Japan (November 2019)

#### In-licensing activities

- Torii to enter into a license agreement with BioCryst Pharmaceuticals, Inc. for BCX7353, a plasma kallikrein inhibitor for the prevention of hereditary angioedema (HAE) attacks (November 2019)
- Torii to sign an exclusive license agreement with JT for co-development and commercialization of tapinarof in Japan (January 2020)

### ③ Maintaining the trust of stakeholders

- Initiatives for enhancing and reinforcing corporate governance and compliance and for responding to various regulations

### Progress

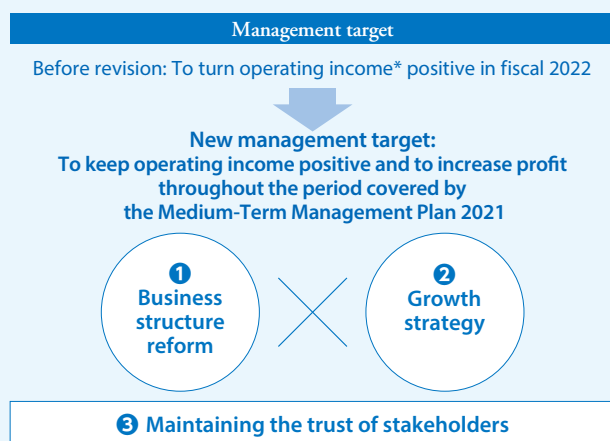
- Establishment of the Nomination and Compensation Advisory Committee as an advisory body for the Board of Directors. (The Committee was abolished on March 26, 2020 as the majority of the Board of Directors consists of independent outside directors.)
- Establishment of the Group for Supervision of Sales Information Provision and the Screening and Supervisory Committee based on the guidelines on sales information provision activities and introduced document screening systems

## Revision of the targets of the Medium-Term Management Plan 2021

The business environment is expected to remain challenging from fiscal 2020 onward owing to NHI drug price revisions and the increasing impact of the growth of generic drugs, and Torii considers that the situation, which does not allow any optimism, will continue. In these circumstances, Torii continues to consider the following items as key managerial issues: ① business structure reform, ② growth strategy, and ③ maintaining the trust of stakeholders.

Meanwhile, in view of the achievement in fiscal 2019, earlier than planned, of the target set by the Medium-Term Management Plan 2021, which was “to turn operating income\* positive in fiscal 2022,” Torii has set a new target, which is “to keep operating income\* positive and to increase profit throughout the period covered by the Medium-Term Management Plan 2021.” And Torii will continue to promote vigorous new business investments to ensure future profit growth.

Regarding distribution of dividends, in accordance with 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, throughout the period covered by the Medium-Term Management Plan 2021, while considering business investments for future growth.



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

## Financial Forecasts for Fiscal 2020

|                                           | December 31, 2019 results | December 31, 2020 targets | Change    | Change (%) |
|-------------------------------------------|---------------------------|---------------------------|-----------|------------|
| <b>Net sales</b> (Millions of yen)        | ¥42,998                   | ¥41,600                   | ¥ (1,398) | (3.3)%     |
| <b>Operating income</b> (Millions of yen) | 1,430                     | 3,000                     | 1,569     | 109.7%     |
| <b>Ordinary income</b> (Millions of yen)  | 1,691                     | 3,300                     | 1,608     | 95.0%      |
| <b>Net income</b> (Millions of yen)       | 27,367                    | 2,100                     | (25,267)  | (92.3)%    |



# Message from the President

## ■ Business Structure Reform Initiatives

With regard to the progress of business structure reforms, which we have set as one of our priority issues, the Company has optimized the number of employees through the implementation of a special program supporting employees who wish to retire voluntarily and embark on a new career, carried out organizational restructuring such as the integration of research and development functions into JT and the consolidation of branch offices in order to optimize organization and functions to suit the scale of business, and restructured its resources so as to focus on maximizing the value of new products, transferring long-listed products such as FUTHAN and URINORM to other companies.

Also, as announced in a press release dated March 18, 2020, the Sakura Plant will be transferred to IWAKI SEIYAKU CO., LTD. on July 1, 2020, and the production of the items produced at the Sakura Plant will be outsourced. We believe that the quality assurance system and technological capabilities that have been established within Sakura Plant will be carried on to IWAKI to maintain the stable supply system.



We will continue to promote further reviews, optimization of resource allocation, thorough efficiency improvements, and more, to create a business structure and organizational culture in which diverse, independent, autonomous, and self-aware employees can maximize their performance.

## ■ Future Growth Strategies

Another of our priority issues is our growth strategy, and as announced in press releases, etc., we have made steady progress in this area.

In the field of renal diseases and hemodialysis, “Riona,” a drug for the treatment of hyperphosphatemia, is currently undergoing a Phase III clinical trial in Japan in collaboration with JT with a new indication for iron deficiency anemia. In July 2019, top-line results from comparative studies were obtained from Phase III clinical trials in Japan. Based on the results of this and other clinical trials, the Company intends to file an additional indication for iron deficiency anemia for “Riona” in Japan. “JTZ-951” is an oral HIF-PH inhibitor being jointly developed in Japan with JT and is indicated for renal anemia. In November 2019, JT filed an application for manufacturing and marketing approval in Japan.

In the field of skin diseases, in January 2020, JT received approval in Japan to manufacture and market to adult patients “CORECTIM® Ointment,” a JAK inhibitor being jointly developed in Japan with JT for the treatment of atopic dermatitis. The Company is working to maximize the value of “CORECTIM® Ointment” in collaboration with JT and expects “CORECTIM® Ointment” will become a new treatment option for atopic dermatitis.

Regarding in-licensing activities, the Company entered into a licensing agreement with BioCryst Pharmaceuticals,

Inc. in November 2019 for exclusive marketing rights in Japan for the prevention of hereditary angioedema (HAE) attacks “BCX7353.” Additionally, we entered into an agreement with JT in January 2020 for the co-development and commercialization of “tapinarof,” a drug in the field of

skin diseases for which JT has exclusive development and commercialization rights to in Japan based on a licensing agreement signed with Dermavant Sciences GmbH. We will continue to work to acquire additional products to ensure future earnings growth.

### Mainstay Research and Development Products (As of February 6, 2020)

| Development code<br>[Product name]                              | Indication                                                       | Formulation/<br>Route of<br>administration | Development stage (domestic) |                                 |           |             |          | Remarks                                                                                                                                                                                                                                                                                                                                                                          |
|-----------------------------------------------------------------|------------------------------------------------------------------|--------------------------------------------|------------------------------|---------------------------------|-----------|-------------|----------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                                                 |                                                                  |                                            | Phase I                      | Phase II                        | Phase III | Application | Approval |                                                                                                                                                                                                                                                                                                                                                                                  |
| <b>Renal diseases and hemodialysis</b>                          |                                                                  |                                            |                              |                                 |           |             |          |                                                                                                                                                                                                                                                                                                                                                                                  |
| <b>JTT-751</b><br>[Riona® Tablets]                              | Iron-deficiency anemia                                           | Oral                                       |                              |                                 | Phase III |             |          | <ul style="list-style-type: none"> <li>● Licensing agreement signed with Keryx for development and commercialization of hyperphosphatemia drug in Japan</li> <li>● Co-development with JT (Additional indication)</li> <li>● Riona filed by JT has been approved as a treatment of hyperphosphatemia in January 2014, and is being promoted and distributed by Torii.</li> </ul> |
| <b>JTZ-951</b>                                                  | Anemia associated with chronic kidney disease                    | Oral                                       |                              |                                 |           | Application |          | <ul style="list-style-type: none"> <li>● JT's original compound</li> <li>● Licensing agreement signed with JT for development and commercialization</li> <li>● NDA filing by JT in November, 2019</li> </ul>                                                                                                                                                                     |
| <b>Skin diseases</b>                                            |                                                                  |                                            |                              |                                 |           |             |          |                                                                                                                                                                                                                                                                                                                                                                                  |
| <b>JTE-052</b><br>[CORECTIM Ointment]                           | Atopic dermatitis                                                | Topical                                    |                              |                                 |           |             | Approval | <ul style="list-style-type: none"> <li>● JT's original compound</li> <li>● Licensing agreement signed with JT for development and commercialization</li> <li>● NDA approval obtained by JT in January, 2020</li> </ul>                                                                                                                                                           |
|                                                                 | Atopic dermatitis in children                                    | Topical                                    |                              |                                 | Phase III |             |          | <ul style="list-style-type: none"> <li>● JT's original compound</li> <li>● Licensing agreement signed with JT for development and commercialization</li> </ul>                                                                                                                                                                                                                   |
| <b>Allergens</b>                                                |                                                                  |                                            |                              |                                 |           |             |          |                                                                                                                                                                                                                                                                                                                                                                                  |
| <b>TO-203</b><br>[MITICURE® House Dust Mite Sublingual Tablets] | House dust mite induced allergic asthma (Allergen Immunotherapy) | Sublingual tablet                          |                              | Phase II/III (Study completed*) |           |             |          | <ul style="list-style-type: none"> <li>● Licensing agreement signed with ALK for providing exclusive development and sales rights in Japan</li> <li>● In-house</li> <li>* Examining the future development policy</li> </ul>                                                                                                                                                     |

#### Additional Information

In January 2020, Torii signed an exclusive license agreement with JT for co-development and commercialization of tapinarof, a topical, therapeutic aryl hydrocarbon receptor modulating agent (TAMA), in Japan. JT signed an exclusive license agreement on January 15, 2020, with Dermavant Sciences GmbH for the development and commercialization of tapinarof for dermatological diseases and conditions in Japan. (Torii and JT will jointly develop tapinarof.)

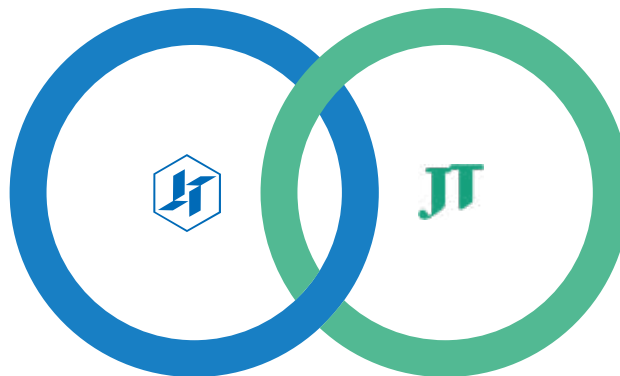
#### Reference

In October 2017, JT announced that the company signed an exclusive license agreement with EirGen Pharma Limited for the development and commercialization in Japan of calcifediol extended-release capsules (marketed by OPKO Health, Inc. in the U.S. under the brand name “RAYALDEE®”) for the treatment of secondary hyperparathyroidism (SHPT) in chronic kidney disease, and Torii is expected to distribute the product after it is approved.

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 the clinical R&D of JT, please refer to the following posted on JT's website: [https://www.jt.com/investors/results/S\\_information/pharmaceuticals/](https://www.jt.com/investors/results/S_information/pharmaceuticals/)

## 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 high-quality 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 medical professionals.

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

In April 2006, Torii assumed responsibility for the JT Group's pharmaceutical manufacturing operations, which have been integrated into our Sakura Plant\*. Some products manufactured at this GMP-certified plant include the topical corticosteroid ANTEBATE OINTMENT and ANTEBATE CREAM. In addition, Torii is responsible for manufacturing investigational new drugs developed by JT.

Importantly, in manufacturing drugs, Torii focuses not only on quality but also on reducing the environmental burden of these operations, as evidenced by the ISO 14001 certification of the Sakura Plant.

We will continue our efforts to ensure a reliable supply of high-quality pharmaceutical products.

\* We have decided on transfer of the Sakura Plant.

### Research and Development

JT is actively investing in 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 by R&D.

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

Torii is working to launch products currently under co-development with JT and maximize their value, as well as to promote the co-development of innovative drugs by acquiring candidates for new in-licensed drugs and strengthening cooperation with JT. To acquire new in-licensed drugs under Torii's flexible strategy with JT, Torii will broaden the target for search and in-licensing to include candidates in and around the franchise areas.

### Mainstay Products



**REMITCH**

Oral antipruritic agent



**Riona**

Agent for hyperphosphatemia

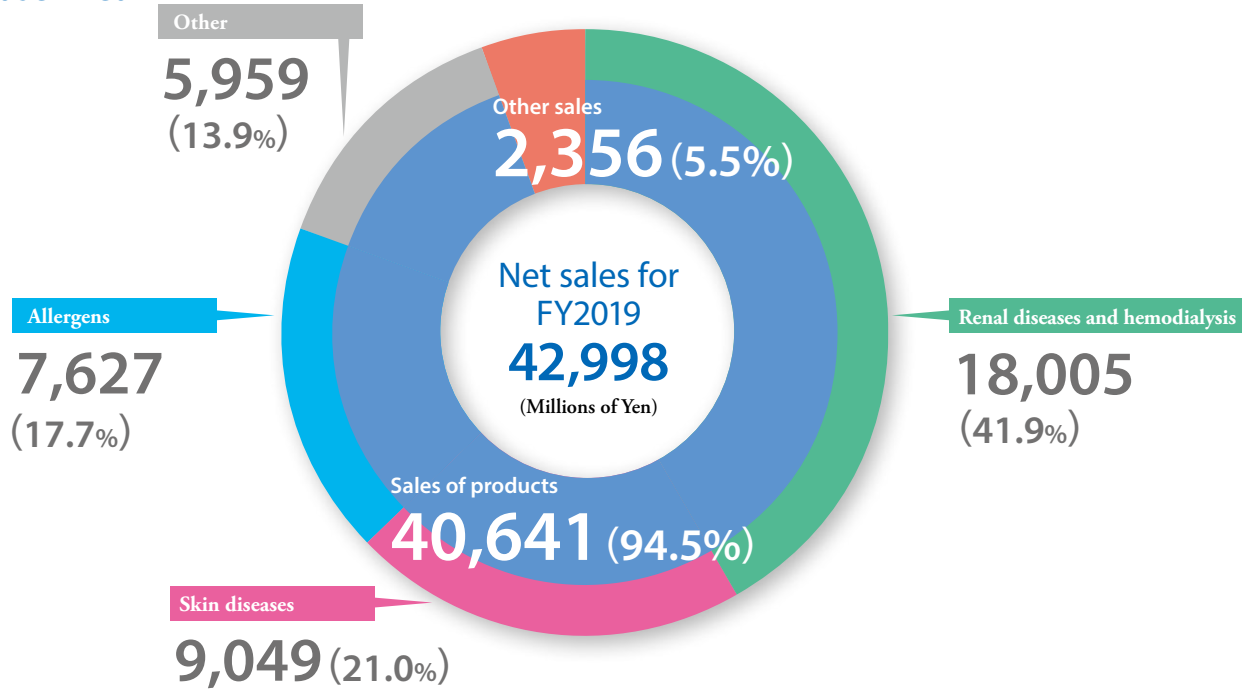


**ANTEBATE**

Topical corticosteroid



## Net Sales by Disease Area



## Net Sales by Mainstay Product

|             |                                                                     | (Millions of Yen) |              |
|-------------|---------------------------------------------------------------------|-------------------|--------------|
|             | Brand name                                                          | FY2018            | FY2019       |
| REMITCH     | Oral antipruritic agent <b>Renal diseases and hemodialysis</b>      | 11,598            | <b>8,693</b> |
| Riona       | Hyperphosphatemia agent <b>Renal diseases and hemodialysis</b>      | 6,603             | <b>6,630</b> |
| ANTEBATE*   | Topical corticosteroid <b>Skin diseases</b>                         | 5,536             | <b>5,439</b> |
| CEDARCURE*  | Japanese cedar pollinosis (Allergen Immunotherapy) <b>Allergens</b> | 405               | <b>3,654</b> |
| MITICURE*   | House dust mite allergy (Allergen Immunotherapy) <b>Allergens</b>   | 1,247             | <b>2,749</b> |
| CEDARTOLEN* | Japanese cedar pollinosis (Allergen Immunotherapy) <b>Allergens</b> | 1,859             | <b>924</b>   |

\* In-house products



**CEDARCURE Japanese Cedar Pollen Sublingual Tablets**  
Japanese cedar pollinosis (Allergen Immunotherapy)



**MITICURE House Dust Mite Sublingual Tablets**  
House dust mite allergy (Allergen Immunotherapy)



**CEDARTOLEN SUBLINGUAL DROP—Japanese Cedar Pollen**  
Japanese cedar pollinosis (Allergen Immunotherapy)

# Corporate Governance

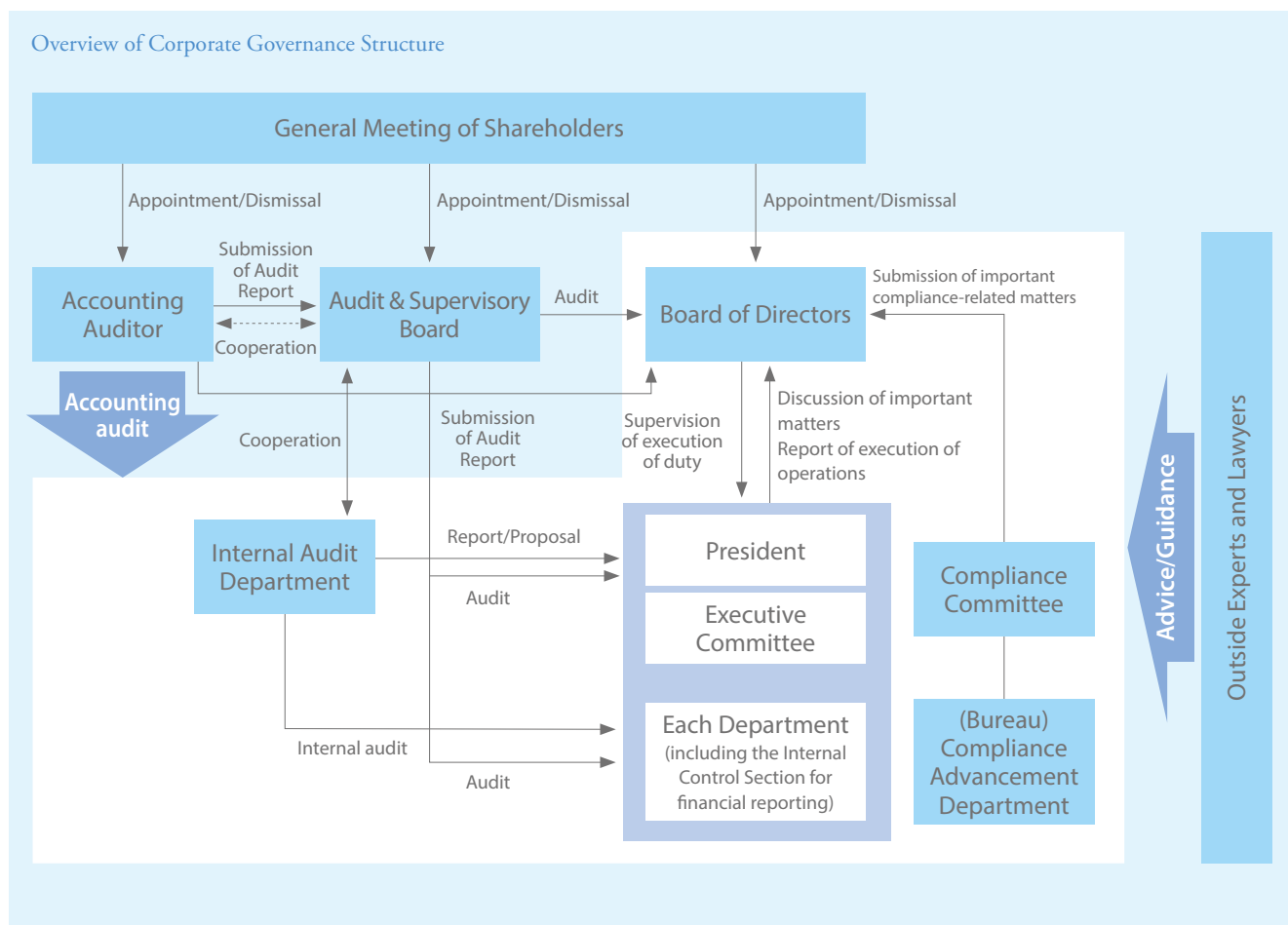
## Basic Stance toward Corporate Governance

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 towards the fulfillment of our corporate mission to contribute to the improvement of human health and to fulfill its responsibilities to customers, shareholders, society and employees, by supplying world-class pharmaceutical products. 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. Based on this philosophy, we have defined a Corporate Governance Policy.

## 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, as well as the Executive Committee, the Compliance Committee, the Compliance Advancement Department and the Internal Audit Department from the perspective of building an effective corporate structure. In addition, Torii considers it appropriate to appoint Independent Outside Directors and Independent Outside Audit & Supervisory Board Members in order to seek out for enhancement of 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)        |
| Selection of Independent Officers*                   | 2 Outside Directors, 2 Outside Audit & Supervisory Board Members |
| Number of Board of Directors meetings in 2019        | 16 times                                                         |
| Number of Audit & Supervisory Board meetings in 2019 | 13 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 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                                                                                                                                                                                                                                                                                                                                                                                                                  |

\* Information as of March 26, 2020.

## Change in Management Structure

On March 26, 2020, the Company revised its management system to further separate management supervision from business execution, in order to enhance corporate governance and boost the efficiency of business execution.

The Board of Directors is composed of a majority of Independent Outside Directors to provide highly effective supervision of management from an independent and objective standpoint. Each Head of Group is assigned the role of executive officers and is responsible for the execution of business operations.

## Evaluation of Effectiveness of the Board of Directors

In fiscal 2019, 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 materials and so on, and deliberation on matters, communication and other items. Questionnaire results as summarized by Independent Outside Directors showed that the items were regarded as generally reasonable and appropriate. Based on these results, we will implement improvements, including further enhancement of communication between Board of Directors members.

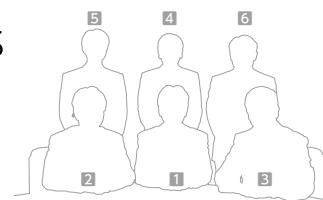
## Matters with Possible Significant Impact on Corporate Governance

JT is Torii's parent company, and owns 54.91% 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. Dividing functions is intended for optimization to realize our corporate mission. 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 its 57 employees to Torii with the aim of improving the efficiency of business operations and enhancing management. However, these employees were dispatched in response to a request from Torii, so that Torii believes that it is able to make independent management decisions.

# Directors and Audit & Supervisory Board Members



Representative Director,  
President and Chief Executive Officer

## Goichi Matsuda 1

- 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)

Standing Audit & Supervisory Board Member

## Ken Yamamoto 4

- Apr. 1984 Joined Japan Tobacco and Salt Public Corporation (currently Japan Tobacco Inc.)
- Apr. 2005 Senior Manager of Business Planning Dept., Pharmaceutical Division of Japan Tobacco Inc.
- Jan. 2016 Senior Manager of Business Administrative Dept., Pharmaceutical Division of Japan Tobacco Inc.
- 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 position)

Member of the Board, Director  
(Outside)

## Masao Torikai 2

- Apr. 1994 Registered as lawyer (The Dai-ichi Tokyo Bar Association)
- Apr. 1994 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)
- Jun. 2016 Outside Director serving as Audit & Supervisory Committee Member of TSUKUI CORPORATION (Current position)

Audit & Supervisory Board Member  
(Outside)

## Eiichi Izumo 5

- Apr. 1995 Joined Tohmatsu & Co. (currently Deloitte Touche Tohmatsu LLC)
- Apr. 1998 Registered as certified public accountant
- Jul. 2010 Partner of Deloitte Touche Tohmatsu LLC
- Feb. 2015 Established Izumo CPA Office Representative (Current position)
- Jun. 2015 Outside Audit & Supervisory Board member of Benesse Holdings, Inc. (Current position)
- Mar. 2016 Audit & Supervisory Board Member of the Company (Current position)

Member of the Board, Director  
(Outside)

## Toshio Fukuoka 3

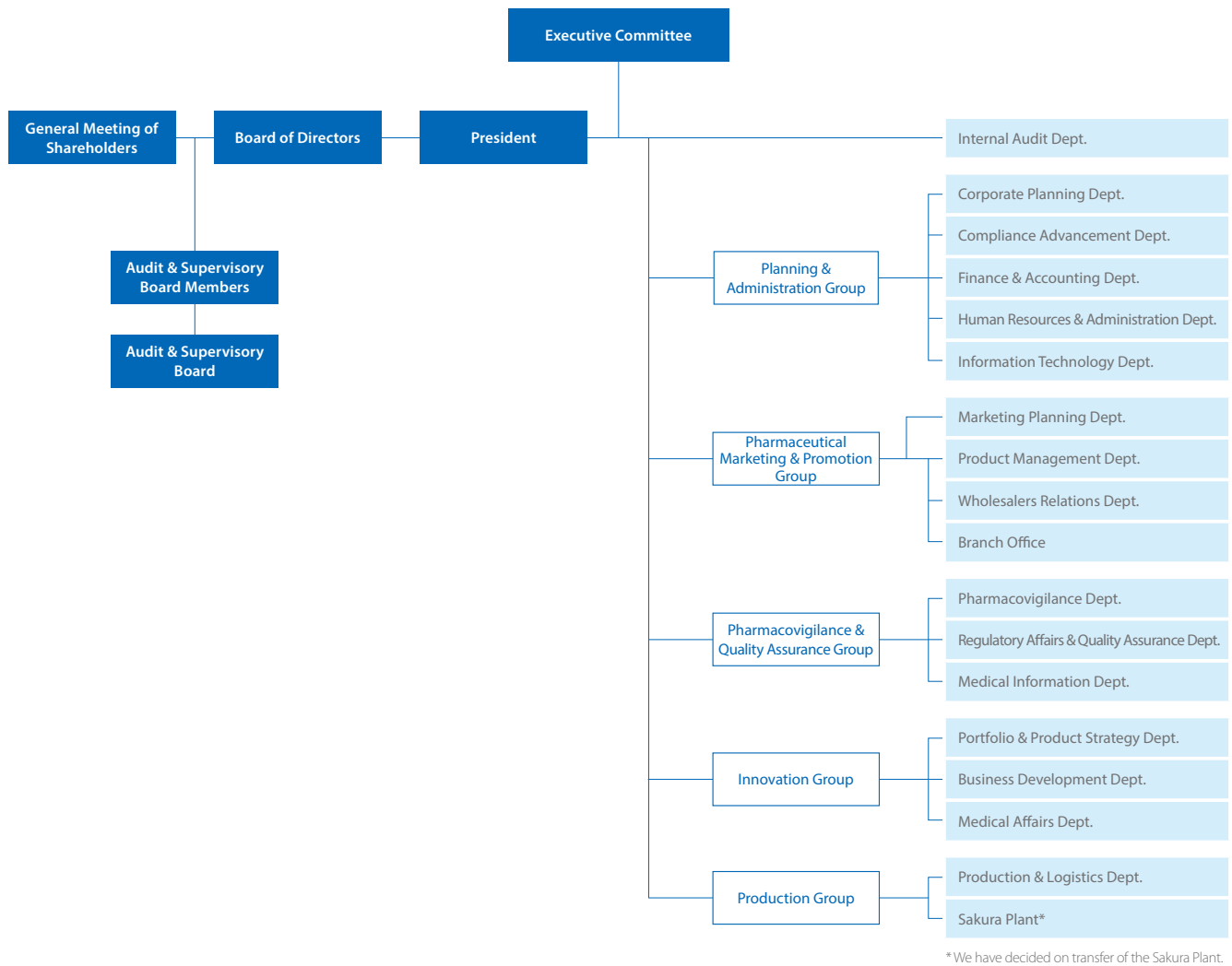
- Apr. 1979 Joined Tokyo Regional Taxation Bureau
- Jul. 2015 Retired from the position of District Director of Kawasaki-Kita Tax Office
- Aug. 2015 Registered as tax accountant, established Toshio Fukuoka Tax Accountant Office Representative (Current position)
- Mar. 2016 Audit & Supervisory Board Member 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)

Audit & Supervisory Board Member  
(Outside)

## Takaharu Matsumura 6

- 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 through office consolidation (Current position)
- Apr. 2017 Outside Audit & Supervisory Board Member of PROPOLIFE GROUP INC. (Current position)
- Mar. 2018 Audit & Supervisory Board Member of the Company (Current position)

# Organization



## Executive Officer List

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



# Dialogue with Outside Directors

## Q Evaluating Management of Torii as an Outside Director

**Torikai** In general, it is difficult for a pharmaceutical company to make major changes to its business and management structure. Up to now, this has applied to our company as well. However, in 2019, licensing agreements for six anti-HIV drugs ended, and sales fell 30%. A company-wide sense of crisis was felt along with an urgent need to change to survive, and discussions at the Board of Directors and in various meetings were conducted with serious exchanges of thoughts regarding the future.

**Fukuoka** Amidst the severe business conditions surrounding the pharmaceutical industry, it was an extremely unique year for our company. Our company has always had the mentality of “getting the most use out of outside directors,” but I felt that attitude was even more prolific this term. In addition to the weekly Executive Committee meetings, we have traditionally attended and expressed our opinions at the Top Discussions, which is more of a free forum for discussion. In fiscal 2019, these Top Discussions were held more frequently than ever. It was President Matsuda’s first year in office, and he began his appointment with a style of making decisions based on the diverse range of views and ideas throughout the Company, as well as the advice from outside perspectives presented in the Top Discussions. In addition, a “Nomination and Compensation Advisory Committee” was established in fiscal 2019 as an advisory body to the Board of Directors, which has improved the transparency of management and the effective functioning of governance.

**Torikai** I agree. There is a great deal of support for us Outside Directors, and I feel that the Company actively

incorporates external perspectives into its management, such as by providing sufficient materials and explanations prior to discussions. On the other hand, the internal control system will have to change due to the new management system that will be introduced in fiscal 2020, which is a subject of further study.

## Q The Role of Outside Directors Under the New Management Structure

**Fukuoka** Under the new management system, the number of directors has been drastically reduced, down to the President and two Outside Directors serving as members on the Board of Directors. Each Head of Group, who also served as a Executive Director, is concentrating on business execution as an Executive Officer. The goal behind this reorganization, in which the majority of the Board of Directors are Outside Directors, is to enhance supervisory and advisory functions not only for nominations and remuneration but also for management overall, while at the same time speeding up the resolution of management issues. I would like to emphasize that this new management structure is a forward-looking approach to strengthening both the accelerator and brakes of management by separating the role of supervision as a director and execution as a head of each group.

**Torikai** It is necessary to shift to an operation similar to a monitoring model, while at the same time transferring significant authority to the Executive Officers. Our company has already decided to abolish its research laboratories and transfer its factories. We will continue to expand our business by maximizing the value of products jointly developed with JT and by acquiring new products. As members of the Board of Directors, we make management decisions from a broad perspective, while Executive Officers

Theme

Under the Medium-Term Management Plan 2021, Torii is promoting the new management system, what kind of company do you intend to

# Transforming Torii from an

serve as frontline leaders and promote initiatives for sustainable growth.

**Fukuoka** In that sense, the role of Outside Director in the Board of Directors will largely be management oversight. By examining the appropriateness of management decisions from the perspective of shareholders and evaluating the results, we will contribute to the improvement of corporate value. I believe that is our duty.

## Q Medium-Term Management Plan 2021 Progress and Future Developments

**Fukuoka** Under the “Medium-Term Management Plan 2021” currently being promoted, we have identified three key issues: business structure reform, growth strategy, and maintaining the trust of stakeholders. During the planned period we were assuming an operating loss, and were aiming to return to profitability in fiscal 2022. Despite the difficult business environment, however, the concerted efforts of all employees have resulted in sales that far exceeded expectations for fiscal 2019, the first year of the plan, and we were able to return to profitability ahead of schedule.

**Torikai** I would like to applaud the hard work of our employees, who achieved more than planned in the midst of the changes accompanying the structural reform of the business. As for our growth strategy, we have been promoting the launch of jointly developed products and the acquisition of new products, but progress moving forward is important and must be carefully monitored.

**Fukuoka** In light of the early achievement of an operating profit, we revised the targets in the Medium-Term Management Plan 2021, setting new targets for continuing operating profit and increasing the profit margin during the planned period. This is actually a difficult goal to achieve,



but there are signs of growth leading to its realization. On the other hand, moving forward it will be important to build a risk management system and strengthen regulatory compliance in order to maintain the trust of stakeholders.

**Torikai** Companies each have their own unique characteristics and unique value creation models. We will continue to make use of external perspectives, offering support for future challenges while considering the best methods of governance for Torii.

**Fukuoka** In order for Torii to achieve further growth, it is essential that governance not only be defensive, but also “offensive”. In addition to my previous experience with the National Tax Agency and the Regional Taxation Bureau, I now have the chance to view numerous companies as a tax accountant as well as both an officer and an advisor for listed companies. I intend to utilize this experience in my duties as an Outside Director to support our company’s efforts to transform itself into a new corporate culture through a bottom-up approach.

business structure reform and growth strategies. After establishing build in the future? Both Outside Directors shared their opinions.

# Pharmaceutical Outside Perspective



# 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 Assurance

#### Quality Management Measures

We have 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. 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.

##### Quality Assurance 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 within Marketing Authorization Holders (Chief Pharmaceutical Officer, Quality Assurance Manager, and Safety Manager). 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.

Diagram on Quality Assurance and Safety Control System



#### Gmp-Based Product Assurance

Good Manufacturing Practices, or GMP, refers to standards for manufacturing control and quality control of pharmaceutical products. Torii uses a quality control system based on GMP to manufacture pharmaceutical products while confirming quality during every process. Manufactured pharmaceutical products are appropriately tested, and only the products that pass this testing are released.

In order to provide pharmaceutical products that patients can feel reassured, we regularly visit manufacturing sites to confirm manufacturing control and quality control with our own eyes. We also share information regarding product quality with each manufacturing site to implement process improvements and quality improvements on a daily basis.

##### Three Principles of GMP

Minimize human error

Prevent contamination and quality deterioration

Design systems that ensure high-quality

#### 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 Chief Pharmaceutical Officer, we report to 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 to Packaging, Labeling and Individual Product Boxes

We engage in discussions with related divisions and consider and revise designs to make packaging and labeling as clear and easy to read as possible as well as improve ease of product identification based on information from medical institutions and patients. We also take measures for medical institutions to dispose of the individual product box more easily by adding the perforated line to the box for scrapping as necessary.

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## 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 duties from the procurement of drug substances (active pharmaceutical ingredients) and other raw materials to manufacturing of pharmaceutical products, inventory optimization, and logistics.

Our ongoing manufacturing measures include the creation of systems in preparation for unforeseen circumstances and the ability to procure drug substances and raw materials from multiple suppliers. We will continue to enhance our supply chain, enabling us to provide the amounts of pharmaceutical products needed, when needed, where needed.

### Measures for Managing Logistics while Ensuring Quality

As a pharmaceutical company, it is our duty to build a system capable of providing patients with a stable supply of safe, high-quality pharmaceutical products manufactured under strict quality control.

Our logistics center stores pharmaceutical products in refrigerated or room-temperature warehouse in accordance with the temperature control category (refrigerated storage or room-temperature storage) defined for each pharmaceutical product. With regard to logistics, from the perspective of transport quality, we exclusively use dedicated vehicles for pharmaceutical product transport (refrigerated trucks for products requiring refrigeration), and can track individual pharmaceutical products through all processes, including manufacturing, storage, and transport, using their serial numbers. We also regularly check temperature control and strive for higher quality logistics management. With regard to risk management, we have envisioned the potential for a large-scale disaster and created a system that uses two logistics centers, one in East Japan and the other in West Japan, such that if one center is affected by the disaster, the other center can continue to supply pharmaceutical products.

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## 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 feedback from our information collected and our analysis is provided on an ongoing, steady basis 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 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 the precautions in the package insert 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 a variety of 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 ensures 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 have worked on human resource development of our MRs so that they can ensure the trust of medical professionals.

We carry out a range of education and training programs to ensure that MRs properly provide and collect information to/from medical professionals with integrity. Regular MR training programs are designed to enable MRs to better leverage their obtained knowledge and skills in the field. MR training status check tools are used to support the growth of each junior MR.

# Customer Support Department

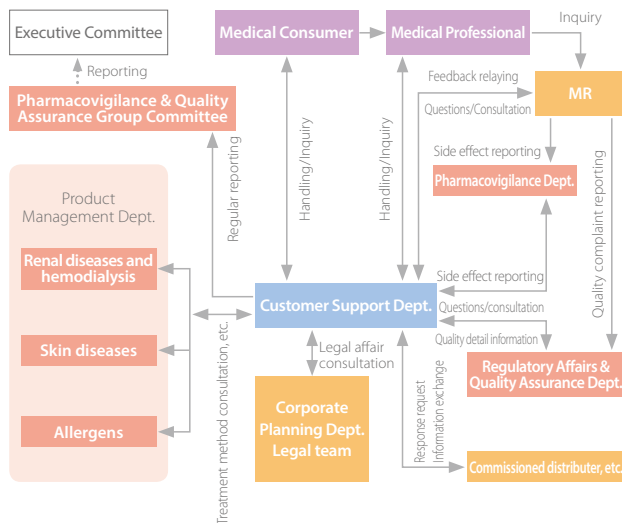
## Customer Support Department Initiatives

Our Customer Support Dept. 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 high-quality, appropriate, scientific-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 Dept. 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. To order to meet customers' expectations, we will continue to reflect customer feedback in product improvements and the provision of high-quality information, contributing to patients' health.

Diagram on Quality Assurance And Safety Control System



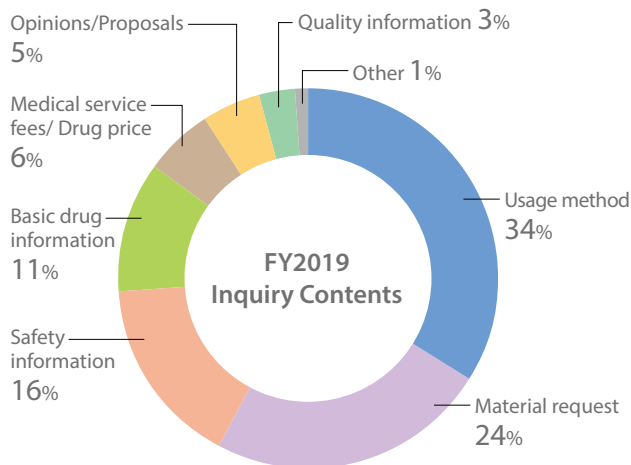
## Customer Support Education

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 learn the same continual training materials that MRs do, and participate actively in study sessions held by related divisions, workshops, and academic society meetings to 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 sites 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 "Senryu de Yomitoku Touseki no Kayumi Taisaku (Learning about Dialysis Pruritus through senryu poems).jp" 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 about 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

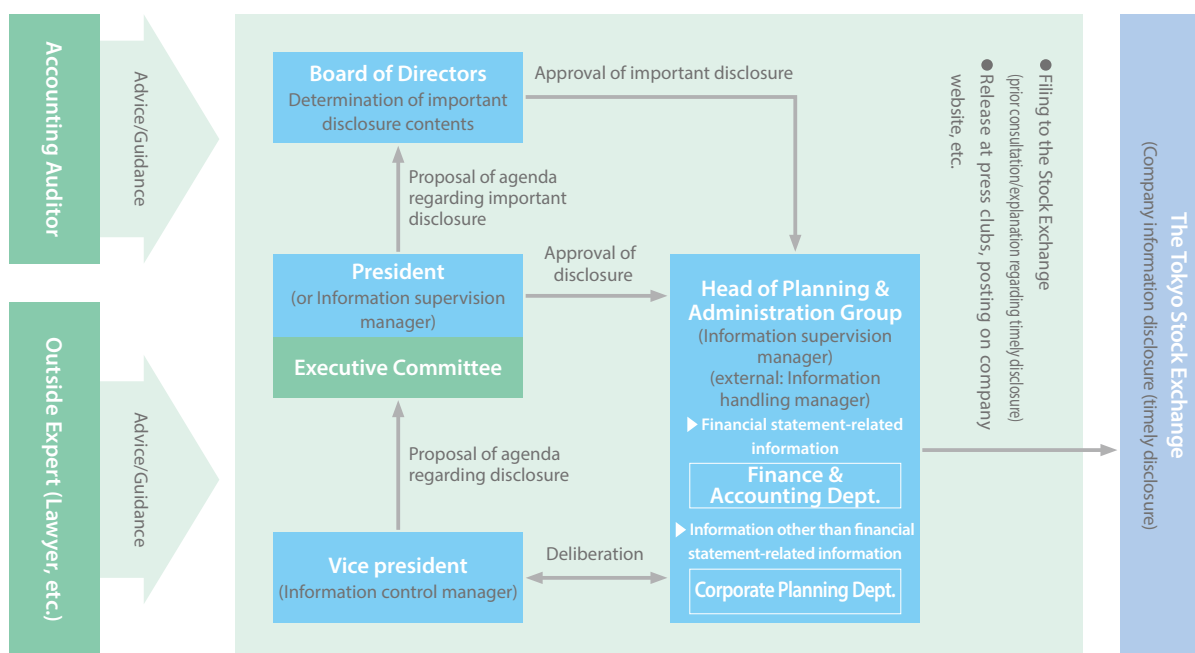
#### Information Disclosure Measures

##### 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 128th General Meeting of Shareholders, held on March 26, 2020, 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 31, 2019<br>Resolution by Board of Directors meeting       | 673                               | 24                       |
| March 26, 2020<br>Resolution by General Meeting of Shareholders | 673                               | 24                       |

Regarding the surplus dividends throughout the three-year period covered by the "Medium-Term Management Plan 2021," in accordance with the basic policy of distributing dividends in a continuous and stable manner, Torii will continue to pay the same level of dividends compared to the previous years.

# CSR Initiatives

## Our Responsibility to Society

We maintain a high ethical standard regarding our corporate social responsibility through business activities that reflect the needs of society.

### Environmental Action Plan

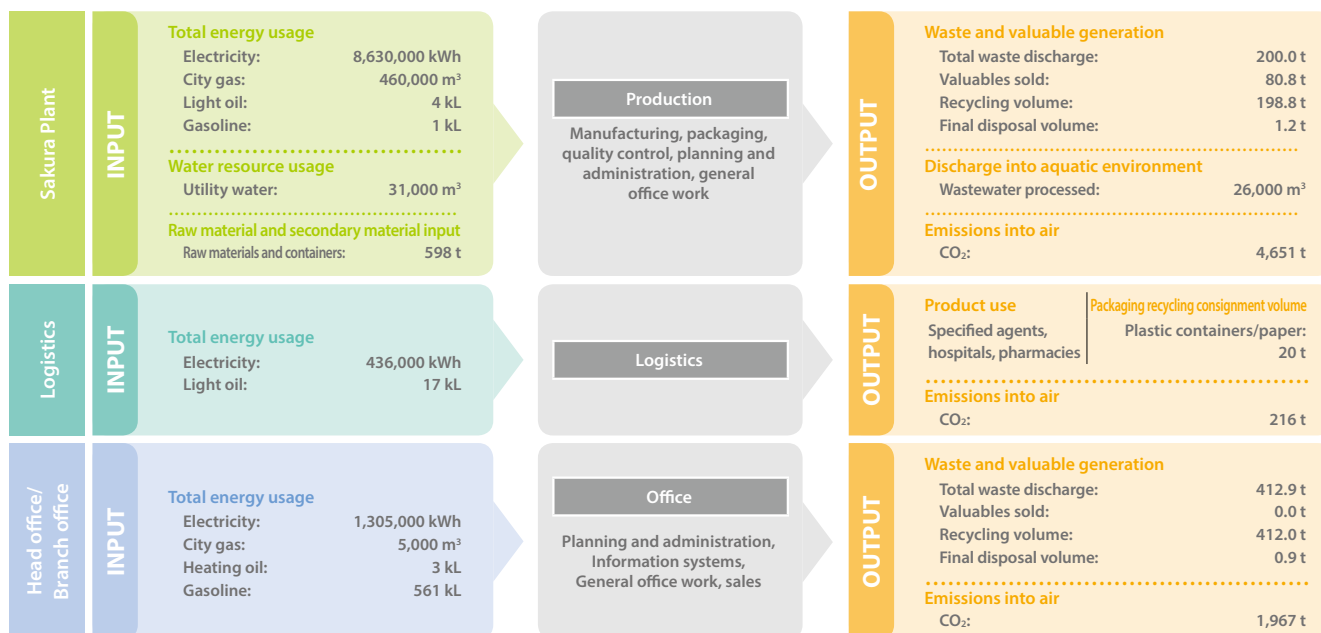
😊 Achieved ☹️ Unachieved

|                                        | FY2019 Environmental Action Plan                                                                                                                                                                                                                                                                                                                                                                                              | FY2019 results                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Evaluation | FY2020 Environmental Action Plan                                                                                                                                                                                                           |
|----------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Greenhouse gas emissions reductions    | Company-wide<br>FY2019 reference value: 6,182t-CO <sub>2</sub> or less                                                                                                                                                                                                                                                                                                                                                        | FY2019 reference value: 6,301t-CO <sub>2</sub>                                                                                                                                                                                                                                                                                                                                                                                                                 | 😊          | FY2020 reference value: 5,975t-CO <sub>2</sub> or less                                                                                                                                                                                     |
|                                        | Sakura Plant<br>FY2019 target: 43t-CO <sub>2</sub> reduction<br>[Main measures]<br>• Switch to LED lighting (No. 1 and No. 2 ointment)<br>• Update multi-split air conditioners<br>• Replace outdoor lights with LED lights<br>• Adjust air volume in AC-3 of No. 4 Plant Bldg.<br>• Implement ISO Working Group Activities (Review air conditioning in product engineering work room, research laboratory, supply warehouse) | FY2019 results: 50t-CO <sub>2</sub> reduction<br>Vs. FY2019 target: 14.0% reduction<br>[Implementation measures]<br>• Switch to LED lighting (No. 1 and No. 2 ointment)<br>• Update multi-split air conditioners<br>• Replace outdoor lights with LED lights<br>• Adjust air volume in AC-3 of No. 4 Plant Bldg.<br>• Implement ISO Working Group Activities (Review air conditioning in product engineering work room, research laboratory, supply warehouse) | 😊          | FY2020 target: 47t-CO <sub>2</sub> reduction<br>[Main measures]<br>• Update air-cooled chillers<br>• Switch to LED lighting at each workplace<br>• Adjust water supply pressure of water pumps<br>• Others include air-conditioning tuning |
|                                        | Head office<br>FY2019 target: 375t-CO <sub>2</sub> or less<br>[Main measures]<br>• Continue installing energy-saving vending machines<br>• Continue implementing Cool Biz and Warm Biz energy-saving initiatives                                                                                                                                                                                                              | FY2019 results: 347t-CO <sub>2</sub><br>Vs. FY2019 target: 7.5% reduction<br>[Implementation measures]<br>• Continue installing energy-saving vending machines<br>• Continue implementing Cool Biz and Warm Biz energy-saving initiatives                                                                                                                                                                                                                      | 😊          | FY2020 target: 375t-CO <sub>2</sub> or less<br>[Main measures]<br>• Continue installing energy-saving vending machines<br>• Continue implementing Cool Biz and Warm Biz energy-saving initiatives                                          |
|                                        | Sales vehicles<br>FY2019 target: 1,502t-CO <sub>2</sub> or less<br>[Main measures]<br>• Continue selecting fuel-efficient vehicles such as hybrids<br>• Continue promotion of eco-drive awareness and education activities                                                                                                                                                                                                    | FY2019 results: 1,303t-CO <sub>2</sub><br>Vs. FY2019 target: 13.2% reduction<br>[Implementation measures]<br>• Continue selecting fuel-efficient vehicles such as hybrids<br>• Continue promotion of eco-drive awareness and education activities                                                                                                                                                                                                              | 😊          | FY2020 target: 1,018t-CO <sub>2</sub> or less<br>[Main measures]<br>• Continue selecting fuel-efficient vehicles such as hybrids<br>• Continue promotion of eco-drive awareness and education activities                                   |
| Reduce water usage                     | Sakura Plant<br>FY2019 target: 31,077m <sup>3</sup> or less<br>[Main measures]<br>• Update wet scrubber                                                                                                                                                                                                                                                                                                                       | FY2019 results: 31,344m <sup>3</sup><br>Vs. FY2019 target: 1.0% reduction<br>[Implementation measures]<br>• Update wet scrubber (Test Bldg., etc.)                                                                                                                                                                                                                                                                                                             | ☹️         | FY2020 target: 31,077m <sup>3</sup> or less<br>[Main measures]<br>• Update wet scrubber (No. 5 Plant Bldg.)                                                                                                                                |
| Maintain/increase waste recycling rate | Sakura Plant<br>FY2019 target: 97% or above<br>[Main measures]<br>• Thorough waste separation<br>• Continue selling off valuables                                                                                                                                                                                                                                                                                             | FY2019 results: 99.4%<br>[Implementation measures]<br>• Thorough waste separation<br>• Continue selling off valuables                                                                                                                                                                                                                                                                                                                                          | 😊          | FY2020 target: 97% or above<br>[Main measures]<br>• Thorough waste separation<br>• Continue selling off valuables                                                                                                                          |
|                                        | Head office<br>FY2019 target: 97% or above<br>[Main measures]<br>• Continue to consign disposal to industrial waste processors with high recycling rates<br>• Continue selling off valuables                                                                                                                                                                                                                                  | FY2019 results: 98.4%<br>[Implementation measures]<br>• Continue to consign disposal to industrial waste processors with high recycling rates<br>• Continue selling off valuables                                                                                                                                                                                                                                                                              | 😊          | FY2020 target: 97% or above<br>[Main measures]<br>• Continue to consign disposal to industrial waste processors with high recycling rates<br>• Continue selling off valuables                                                              |

In terms of results of the Environmental Action Plan for fiscal 2019, the target for water consumption at the Sakura Plant was not achieved. The

cause was a temporary increase in consumption due to deterioration of water supply piping. All other targets for fiscal 2019 were achieved.

### Overview of Business Activities and Their Environmental Impacts



## Compliance Measures

### 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 compliance-oriented activities.

### Compliance Promotion Structure

Torii defines the promotion of compliance as one of the key management issues involved in achieving its corporate mission. After creating its compliance structure in September 2001, Torii established Compliance Committee in 2004. This committee deliberates regarding compliance promotion issues. In order to further enhance company compliance, Torii established Medical Compliance Department in August 2014. This department is responsible for reviewing clinical research and Torii's academic information materials. In January 2015, Torii formed Compliance Advancement Department, responsible for company-wide compliance promotion operations. In October 2019, the two departments were merged for greater efficiency and effectiveness.

### 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 satisfy our responsibility to society through our activities, which are based on these guidelines.

# CSR Initiatives

## Our Responsibility to Employees

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.

### Personnel Development

In order to create a stronger organization, we carry out training, focused on management and mid-level employees, with the aim of enhancing their development and management related skills and knowledge in areas such as subordinate development, encouraging teams, and providing instruction to junior colleagues. Together with elective training and distance learning for which employees apply, we are conducting ongoing, systematic personnel development. We have also introduced systems that provide training follow-up to ensure that participants can leverage their knowledge and skills in their work.

In addition, we offer 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. Subsidies are provided to employees who have satisfied program completion requirements.

Training Participation Results (Fiscal 2019)

| Learning and training                                         | Number of participants |
|---------------------------------------------------------------|------------------------|
| Life planning training (information provision)                | 0 [34]                 |
| Topic-specific training (business basics, team power, global) | 15 [36]                |
| Management training                                           | 10 [55]                |
| Position-specific training (excluding new employee training)  | 120 [298]              |
| New employee training                                         | 16 [38]                |
| Distance learning (self-improvement)                          | 122 [113]              |

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

Work Style Reform Measures

| Item                                                                             | Overview                                                                                                                                                          |
|----------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Institutionalization of two-hour paid leave                                      | In addition to daily or half-day units, any two-hour unit can be acquired.                                                                                        |
| Flexible use of working hours<br>Institutionalization of staggered working hours | To enable a shift in the start and end of working hours according to work patterns without changing the prescribed working hours per day (7 hours and 50 minutes) |
| Establishment of a system for transportation of children by sales vehicles       | Sales vehicles can be used only when children under elementary school age are taken to and from nursery and other schools.                                        |

Status of Measures for Promoting Active Participation by Female Employees

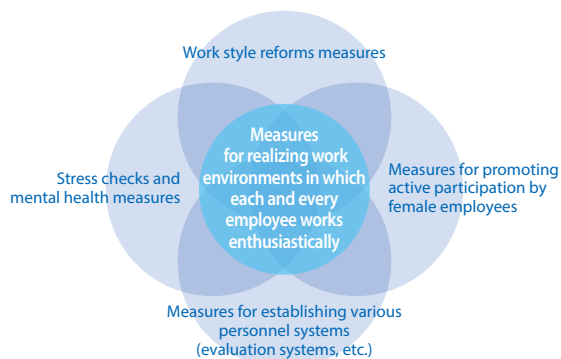
| Item                                                        | As of December 31, 2019                                                  |
|-------------------------------------------------------------|--------------------------------------------------------------------------|
| Percentage of women in the board members                    | 10.0% [7.1%]                                                             |
| Percentage of women in management positions                 | 8.1% [6.4%]                                                              |
| Percentage of women in all employees                        | 21.7% [20.9%]                                                            |
| Percentage of women in newly-hired employees                | 27.8% [32.5%]                                                            |
| Average years of service between Male vs Female             | Men: 13.8 years Women: 10.3 years<br>[Men: 14.0 years Women: 10.6 years] |
| Average overtime per month                                  | 13.8 hours [13.5 hours]                                                  |
| Rate of taking annual paid leave (April 2019 to March 2020) | 80.2% [73.6%]                                                            |

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

## Creating Better Working Environments

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

Torii has engaged in various activities, such as (1) work style reforms measures, (2) measures for promoting active participation by female employees, (3) measures for establishing various personnel systems (evaluation systems, etc.), and (4) stress checks and mental health measures. These are all measures for realizing work environments in which each and every employee works enthusiastically. By sincerely addressing each of these activities, we are creating a pleasant work environment even under the restricted circumstances including pregnancy, child-birth, child-raising and nursing care. This enables our driven, skilled employees to maintain their high levels of motivation and leverage their abilities, contributing to sustained growth for the employees and the company.



### Human Rights Measures

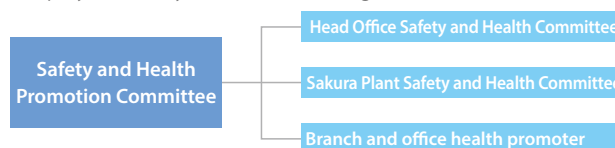
We believe it is important that people working in the same workplaces respect one another and build relationships of mutual trust, and that as members of society all people always respect the rights of others. This is why on December 10, Human Rights Day, we carry out measures aimed at developing a shared 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.

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 Organization



\* A Safety and Health Committee is established for worksites with 50 or more full-time workers

\* 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 |         |         |         |
|-----------------------------------------------------|-----------------|---------|---------|---------|
|                                                     | March 31        |         |         |         |
|                                                     | 2011            | 2012    | 2013    | 2014    |
| <b>For the Year</b>                                 |                 |         |         |         |
| Net sales                                           | ¥45,335         | ¥48,717 | ¥52,294 | ¥58,109 |
| Gross profit                                        | 26,732          | 28,178  | 29,452  | 31,842  |
| Operating income                                    | 1,844           | 4,153   | 2,794   | 4,987   |
| Income before income taxes                          | 1,839           | 5,054   | 2,929   | 5,133   |
| Net income                                          | 937             | 2,611   | 1,849   | 3,352   |
| Capital expenditures                                | 797             | 849     | 1,374   | 1,202   |
| Research and development costs                      | 5,994           | 4,631   | 7,824   | 6,662   |
| Net cash provided by (used in) operating activities | (516)           | 3,040   | 151     | (201)   |
| Net cash provided by (used in) investing activities | (21,302)        | 3,151   | 874     | 17,706  |
| Net cash used in financing activities               | (1,243)         | (1,154) | (1,181) | (1,319) |

|                                     |         |         |         |         |
|-------------------------------------|---------|---------|---------|---------|
| <b>At Fiscal Year-End</b>           |         |         |         |         |
| Total assets                        | ¥84,885 | ¥87,734 | ¥91,350 | ¥93,137 |
| Total equity                        | 74,246  | 75,832  | 76,700  | 79,018  |
| Number of shares issued (Thousands) | 28,800  | 28,800  | 28,800  | 28,800  |
| Number of employees                 | 905     | 927     | 969     | 1,009   |

|                       | Yen      |          |          |          |
|-----------------------|----------|----------|----------|----------|
| <b>Per Share Data</b> |          |          |          |          |
| Total equity          | ¥2,623.4 | ¥2,679.5 | ¥2,710.2 | ¥2,792.1 |
| Net income            | 33.1     | 92.3     | 65.4     | 118.5    |
| Cash dividends        | 40       | 40       | 40       | 40       |

|                            | %     |      |      |      |
|----------------------------|-------|------|------|------|
| <b>Key Ratios</b>          |       |      |      |      |
| Operating income ratio     | 4.1   | 8.5  | 5.3  | 8.6  |
| Return on equity (ROE)     | 1.3   | 3.5  | 2.4  | 4.3  |
| Return on assets (ROA)     | 1.1   | 3.0  | 2.1  | 3.6  |
| Shareholders' equity ratio | 87.5  | 86.4 | 84.0 | 84.8 |
| Dividend payout ratio      | 120.8 | 43.4 | 61.2 | 33.8 |

\*1 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 ¥109.56.00=US\$1.00, the approximate exchange rate prevailing on December 31, 2019.

\*2 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.

| Millions of Yen    |          |          |          |          |                  | Thousands of U.S. Dollars*1 |
|--------------------|----------|----------|----------|----------|------------------|-----------------------------|
| December 31 2014*2 | 2015     | 2016     | 2017     | 2018     | December 31 2019 | December 31 2019            |
| ¥43,504            | ¥62,378  | ¥60,206  | ¥64,135  | ¥62,551  | ¥42,998          | \$392,462                   |
| 22,917             | 31,564   | 29,919   | 32,841   | 30,707   | 22,295           | 203,500                     |
| 4,032              | 4,919    | 3,819    | 6,281    | 4,951    | 1,430            | 13,058                      |
| 3,781              | 5,258    | 4,056    | 6,373    | 3,030    | 37,700           | 344,109                     |
| 2,419              | 3,527    | 2,839    | 4,718    | 1,164    | 27,367           | 249,792                     |
| 1,514              | 2,207    | 891      | 931      | 811      | 330              | 3,015                       |
| 3,400              | 5,237    | 4,654    | 4,608    | 4,138    | 2,956            | 26,989                      |
| (609)              | 4,940    | 3,402    | 6,349    | 8,259    | 42,499           | 387,910                     |
| 499                | 957      | 1,361    | (7,593)  | (27,068) | 2,099            | 19,161                      |
| (1,410)            | (1,582)  | (2,289)  | (1,546)  | (1,432)  | (1,433)          | (13,086)                    |
| ¥92,550            | ¥98,868  | ¥98,525  | ¥104,741 | ¥103,253 | ¥139,943         | \$1,277,326                 |
| 80,225             | 82,826   | 83,556   | 87,119   | 87,092   | 113,125          | 1,032,547                   |
| 28,800             | 28,800   | 28,800   | 28,800   | 28,800   | 28,800           | 28,800                      |
| 1,047              | 1,058    | 1,059    | 1,074    | 1,049    | 660              | 660                         |
| Yen                |          |          |          |          |                  | U.S. Dollars*1              |
| ¥2,834.8           | ¥2,926.8 | ¥2,978.8 | ¥3,105.7 | ¥3,103.3 | ¥4,029.3         | \$36.78                     |
| 85.5               | 124.7    | 100.4    | 168.2    | 41.5     | 975.0            | 8.90                        |
| 40                 | 48       | 48       | 48       | 48       | 48               | 0.44                        |
| %                  |          |          |          |          |                  |                             |
| 9.3                | 7.9      | 6.3      | 9.8      | 7.9      | 3.3              |                             |
| 3.0                | 4.3      | 3.4      | 5.5      | 1.3      | 27.3             |                             |
| 2.6                | 3.7      | 2.9      | 4.6      | 1.1      | 22.5             |                             |
| 86.7               | 83.8     | 84.8     | 83.2     | 84.3     | 80.8             |                             |
| 46.8               | 38.5     | 47.8     | 28.5     | 115.6    | 4.9              |                             |

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

## Financial Results for the Year Ended December 31, 2019

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, with the promotion of health care system reforms, there has been an urgent need to curb healthcare expenditures, such as through drastic reform of the drug pricing system and encouragement of greater use of generic drugs. Moreover, the termination of the exclusive rights to market six anti-HIV drugs in Japan had a strong financial impact on Torii.

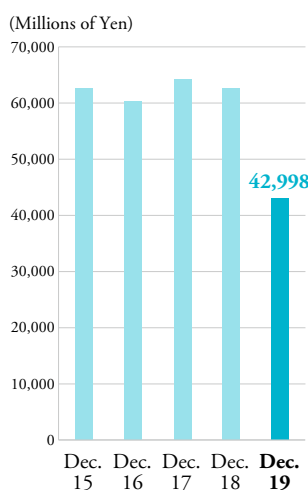
With a view to such an increasingly challenging business environment, Torii established the Medium-Term Management Plan 2021 with the aim of turning operating income positive in fiscal 2022 and continuously generating profit thereafter. (This excludes expenses relating to new business investments, which include investments to acquire new in-licensed drugs and M&A.) In accordance with the plan, Torii has been promoting initiatives aimed at drastic improvement of its profit structure through business structure reform and medium- to long-term growth.

### Net Sales

Net sales decreased by ¥19,553 million (31.3%) over the previous corresponding period to ¥42,998 million. This was mainly due to the transfer of sales rights for six anti-HIV drugs in January 2019.

As for sales excluding those in the HIV infection area, Torii sought to maintain and expand its existing products in the franchise areas of renal disease and hemodialysis, skin disease and the allergens. Accordingly, net sales increased by ¥1,895 million (4.6%) to ¥42,998 million. This was mainly due to higher sales in CEDARTOLEN SUBLINGUAL DROP—Japanese Cedar Pollen and MITICURE House Dust Mite Sublingual Tablets (allergen immunotherapy) in the allergens area as well as the recording of distribution fees for the six anti-HIV drugs handled by the Company as a transitional measure in connection with the transfer of sales rights for them, partly offset by the impact of generic products of REMITCH (an oral antipruritic agent for hemodialysis patients).

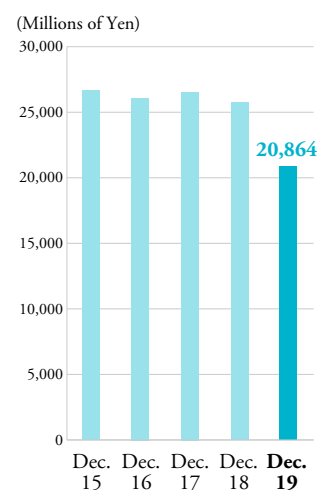
Net Sales



Sales of Mainstay Products

|           | Dec. 2018 | Dec. 2019 | Change              |
|-----------|-----------|-----------|---------------------|
| REMITCH   | ¥11,598   | ¥8,693    | ¥(2,904)<br>(25.0)% |
| Riona     | 6,603     | 6,630     | 27<br>0.4%          |
| ANTEBATE  | 5,536     | 5,439     | (97)<br>(1.8)%      |
| CEDARCURE | 405       | 3,654     | 3,249<br>801.8%     |
| MITICURE  | 1,247     | 2,749     | 1,502<br>120.4%     |

Selling, General and Administrative Expenses



Sales of mainstay products in franchise areas were as follows:

- In the renal disease and hemodialysis area, sales of REMITCH decreased by ¥2,904 million (25.0%) to ¥8,693 million, affected by generic products. Sales of Riona Tablets (a therapeutic agent for hyperphosphatemia) rose ¥27 million (0.4%) to ¥6,630 million.
- In the skin disease area, sales of ANTEBATE (a topical corticosteroid) declined by ¥97 million (1.8%) to ¥5,439 million.
- In the allergens area, sales of MITICURE House Dust Mite Sublingual Tablets increased by ¥1,502 million (120.4%) to ¥2,749 million, due to the further spread of allergen immunotherapy, and CEDARCURE Japanese Cedar Pollen Sublingual Tablets, launched in June 2018, amounted to ¥3,654 million. Sales of CEDARTOLEN SUBLINGUAL DROP—Japanese Cedar Pollen (allergen immunotherapy) fell by ¥935 million (50.3%) to ¥924 million.

### Cost of Sales

Cost of sales decreased by ¥11,141 million (35.0%) to ¥20,702 million, mainly due to lower net sales.

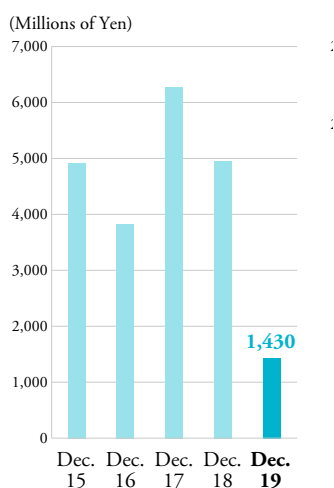
### Selling, General and Administrative (SG&A) Expenses

SG&A expenses decreased by ¥4,890 million (19.0%) to ¥20,864 million, primarily as the result of a decline in sales-related expenses and R&D expenses, reduction of personnel expenses reflecting implementation of the implementation of a special program supporting employees' career changes, and reduced costs.

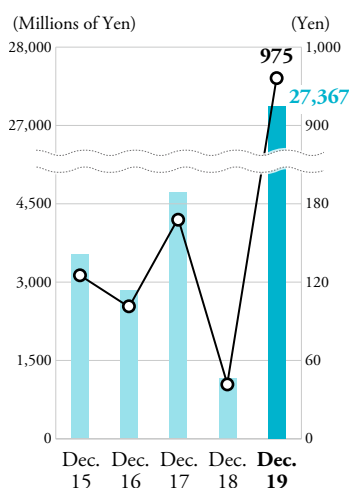
### Operating Income and Net Income

As a result of the above, operating income was ¥1,430 million, a decrease of ¥3,520 million (71.1%) over the previous corresponding period. Net income was ¥27,367 million, an increase of ¥26,202 million over the previous corresponding period. This principally reflected the recording of a ¥40,614 gain on transfer of sales rights for six anti-HIV drugs in Other Income, which is partly offset by additional severance costs of ¥4,504 million for the implementation of a special program supporting employees' career changes recorded as business structure reform expenses in Other Expenses.

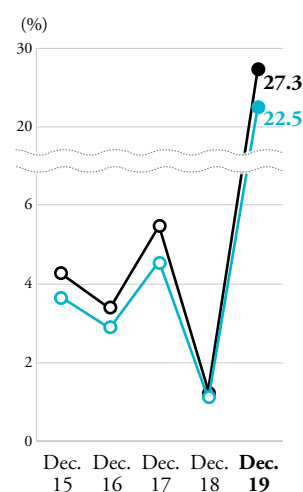
#### Operating Income



#### Net Income and Net Income per Share



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



## Financial Position at December 31, 2019

### Assets, Liabilities and Equity

Total assets increased by ¥36,690 million (35.5%) from the end of the previous fiscal year to ¥139,943 million as of December 31, 2019. Current assets rose by ¥31,564 million (40.2%) to ¥110,017 million, mainly due to a ¥43,165 million increase in cash and cash equivalent and a ¥7,704 million increase in marketable securities despite a ¥1,997 million decrease in trade accounts receivable. Net property, plant and equipment decreased by ¥653 million (19.0%) to ¥2,778 million. Investment and other assets rose by ¥5,779 million (27.0%) to ¥27,147 million mainly due to a ¥5,993 million increase in investment securities.

Total liabilities rose by ¥10,657 million (65.9%) to ¥26,817 million. Reasons for this change included a ¥8,983 million increase in income taxes payable and a ¥2,885 million increase in consumption tax payable included in Other Current Liabilities in Current Liabilities.

Total equity rose by ¥26,033 million (29.9%) to ¥113,125 million. Contributing factors included surplus dividends of ¥1,347 million and net income of ¥27,367 million.

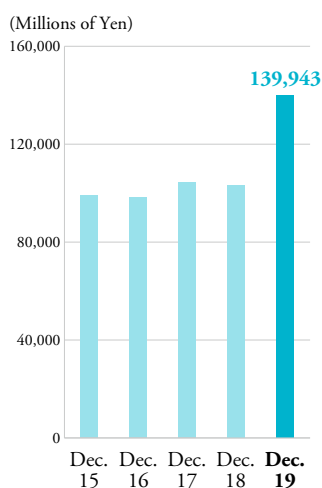
## Cash Flows for the Year Ended December 31, 2019

At ¥58,819 million, cash and cash equivalents as of December 31, 2019 were ¥43,165 million (275.7%) higher than at the end of the previous fiscal year.

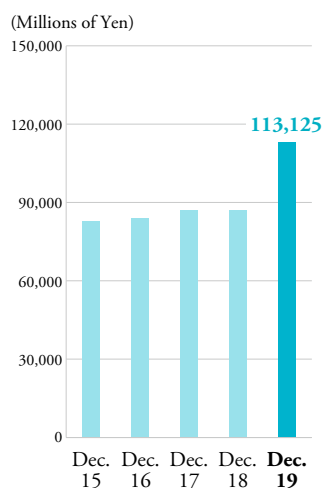
### Cash Flows from Operating Activities

Net cash provided by operating activities amounted to ¥42,499 million. (Net cash provided by operating activities for the previous corresponding year totaled ¥8,259 million.) This result reflected income before income taxes of ¥37,700 million, depreciation and amortization of ¥985 million, a ¥2,885 million increase in consumption tax payable, a ¥1,986 million decrease in trade notes and accounts receivable, a ¥801 million decrease in inventories, a ¥1,936 million increase in long-term prepaid expenses and income taxes paid of ¥1,401 million.

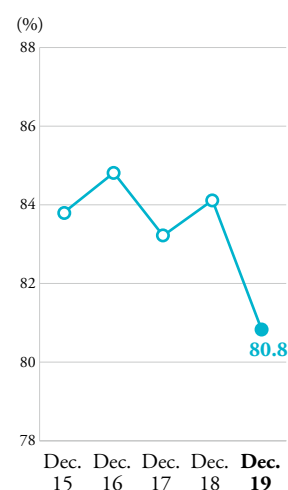
Total Assets



Total Equity



Shareholders' Equity Ratio



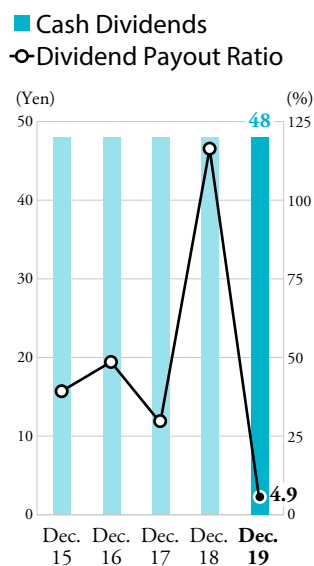
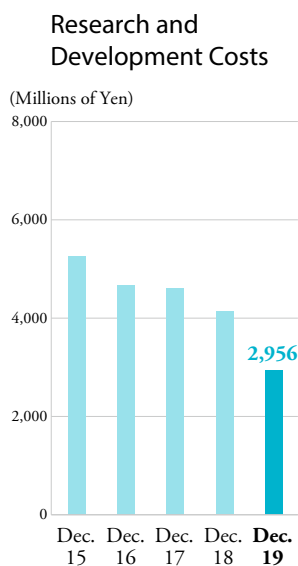


### Cash Flows from Investing Activities

Net cash provided by investing activities amounted to ¥2,099 million. (Net cash used in investing activities for the previous corresponding year totaled ¥27,068 million.) Major items included inflows of ¥44,300 million in proceeds from sale and redemption of marketable securities and of ¥1,903 million in proceeds from sale and redemption of investment securities. These inflows were partly offset by outflows of ¥31,713 million in purchases of marketable securities and ¥11,853 million in purchases of investment securities.

### Cash Flows from Financing Activities

Net cash used in financing activities amounted to ¥1,433 million, consisting mainly of ¥1,347 million in dividends paid. (Net cash used in financing activities for the previous corresponding period totaled ¥1,432 million.)



# Balance Sheet

|                                             | Millions of Yen      |                      | Thousands of<br>U.S. Dollars (Note 1) |
|---------------------------------------------|----------------------|----------------------|---------------------------------------|
|                                             | December 31,<br>2019 | December 31,<br>2018 | December 31,<br>2019                  |
| <b>ASSETS</b>                               |                      |                      |                                       |
| <b>CURRENT ASSETS:</b>                      |                      |                      |                                       |
| Cash and cash equivalents (Notes 12 and 13) | ¥ 58,819             | ¥ 15,654             | \$ 536,867                            |
| Marketable securities (Notes 3 and 12)      | 17,901               | 25,606               | 163,394                               |
| Receivables (Note 12):                      |                      |                      |                                       |
| Trade notes                                 | 14                   |                      | 133                                   |
| Trade accounts                              | 25,096               | 27,094               | 229,069                               |
| Parent                                      | 137                  | 975                  | 1,259                                 |
| Other                                       | 267                  | 137                  | 2,444                                 |
| Inventories (Note 4)                        | 7,513                | 8,315                | 68,578                                |
| Prepaid expenses and other current assets   | 266                  | 670                  | 2,430                                 |
| Total current assets                        | 110,017              | 78,453               | 1,004,177                             |
| <b>PROPERTY, PLANT AND EQUIPMENT:</b>       |                      |                      |                                       |
| Land                                        | 446                  | 446                  | 4,071                                 |
| Buildings and structures                    | 10,324               | 10,274               | 94,237                                |
| Machinery and equipment                     | 7,384                | 8,079                | 67,400                                |
| Furniture and fixtures                      | 1,933                | 2,150                | 17,644                                |
| Lease assets (Note 11)                      | 1,977                | 1,977                | 18,050                                |
| Construction in progress                    | 9                    | 99                   | 90                                    |
| Total                                       | 22,075               | 23,027               | 201,495                               |
| Accumulated depreciation                    | (19,297)             | (19,595)             | (176,134)                             |
| Net property, plant and equipment           | 2,778                | 3,431                | 25,360                                |
| <b>INVESTMENTS AND OTHER ASSETS:</b>        |                      |                      |                                       |
| Investment securities (Notes 3 and 12)      | 19,764               | 13,770               | 180,399                               |
| Software                                    | 420                  | 567                  | 3,835                                 |
| Long-term prepaid expenses                  | 5,207                | 4,793                | 47,531                                |
| Deferred tax assets (Note 9)                | 1,174                | 1,494                | 10,716                                |
| Other assets                                | 581                  | 742                  | 5,304                                 |
| Total investments and other assets          | 27,147               | 21,368               | 247,787                               |
| <b>TOTAL</b>                                | <b>¥139,943</b>      | <b>¥103,253</b>      | <b>\$1,277,326</b>                    |

See notes to financial statements.

|                                                                                                    | Millions of Yen      |                      | Thousands of<br>U.S. Dollars (Note 1) |
|----------------------------------------------------------------------------------------------------|----------------------|----------------------|---------------------------------------|
|                                                                                                    | December 31,<br>2019 | December 31,<br>2018 | December 31,<br>2019                  |
| <b>LIABILITIES AND EQUITY</b>                                                                      |                      |                      |                                       |
| <b>CURRENT LIABILITIES:</b>                                                                        |                      |                      |                                       |
| Payables (Note 12):                                                                                |                      |                      |                                       |
| Trade accounts                                                                                     | ¥ 3,862              | ¥ 3,714              | \$ 35,257                             |
| Parent (Note 13)                                                                                   | 2,155                | 3,441                | 19,675                                |
| Other                                                                                              | 4,282                | 3,579                | 39,088                                |
| Current portion of long-term lease obligations                                                     | 85                   | 85                   | 780                                   |
| Income taxes payable (Note 12)                                                                     | 9,836                | 852                  | 89,777                                |
| Accrued expenses                                                                                   | 347                  | 757                  | 3,171                                 |
| Accrued employees' bonuses                                                                         | 444                  | 675                  | 4,054                                 |
| Accrued bonuses to directors and Audit & Supervisory Board members                                 | 37                   | 63                   | 339                                   |
| Other current liabilities                                                                          | 3,890                | 1,105                | 35,513                                |
| Total current liabilities                                                                          | 24,942               | 14,274               | 227,657                               |
| <b>LONG-TERM LIABILITIES:</b>                                                                      |                      |                      |                                       |
| Liability for retirement benefits (Note 6)                                                         | 1,150                | 1,077                | 10,497                                |
| Long-term lease obligations                                                                        | 294                  | 380                  | 2,692                                 |
| Asset retirement obligations                                                                       | 148                  | 151                  | 1,350                                 |
| Other long-term liabilities                                                                        | 282                  | 276                  | 2,580                                 |
| Total long-term liabilities                                                                        | 1,875                | 1,885                | 17,120                                |
| <b>EQUITY (Notes 7 and 8):</b>                                                                     |                      |                      |                                       |
| Common stock—authorized, 54,000,000 shares;<br>issued, 28,800,000 shares in December 2019 and 2018 | 5,190                | 5,190                | 47,371                                |
| Capital surplus:                                                                                   | 6,429                | 6,426                | 58,682                                |
| Additional paid-in capital                                                                         | 6,416                | 6,416                | 58,561                                |
| Other capital surplus                                                                              | 13                   | 10                   | 120                                   |
| Stock acquisition rights                                                                           | 11                   | 11                   | 103                                   |
| Retained earnings:                                                                                 |                      |                      |                                       |
| Legal reserve                                                                                      | 1,297                | 1,297                | 11,842                                |
| Unappropriated                                                                                     | 100,779              | 74,759               | 919,853                               |
| Unrealized gain on available-for-sale securities                                                   | 850                  | 864                  | 7,761                                 |
| Treasury stock—at cost, 726,961 shares in December 2019 and<br>738,846 shares in December 2018     | (1,431)              | (1,455)              | (13,066)                              |
| Total equity                                                                                       | 113,125              | 87,092               | 1,032,547                             |
| <b>TOTAL</b>                                                                                       | <b>¥ 139,943</b>     | <b>¥ 103,253</b>     | <b>\$1,277,326</b>                    |

# Statement of Income

Torii Pharmaceutical Co., Ltd.  
Year ended December 31, 2019

|                                                                              | Millions of Yen                    |                                    | Thousands of<br>U.S. Dollars (Note 1) |
|------------------------------------------------------------------------------|------------------------------------|------------------------------------|---------------------------------------|
|                                                                              | Year Ended<br>December 31,<br>2019 | Year Ended<br>December 31,<br>2018 | Year Ended<br>December 31,<br>2019    |
| <b>NET SALES</b>                                                             | <b>¥ 42,998</b>                    | ¥ 62,551                           | <b>\$ 392,462</b>                     |
| <b>COST OF SALES</b> (Notes 6, 11 and 13)                                    | <b>20,702</b>                      | 31,844                             | <b>188,961</b>                        |
| Gross profit                                                                 | <b>22,295</b>                      | 30,707                             | <b>203,500</b>                        |
| <b>SELLING, GENERAL AND ADMINISTRATIVE<br/>EXPENSES</b> (Notes 6, 10 and 11) | <b>20,864</b>                      | 25,755                             | <b>190,442</b>                        |
| Operating income                                                             | <b>1,430</b>                       | 4,951                              | <b>13,058</b>                         |
| <b>OTHER INCOME (EXPENSES):</b>                                              |                                    |                                    |                                       |
| Interest and dividend income                                                 | <b>221</b>                         | 76                                 | <b>2,021</b>                          |
| Gain on transfer of sales rights (Note 13)                                   | <b>40,614</b>                      |                                    | <b>370,708</b>                        |
| Loss on disposal of property, plant and equipment (Note 1)                   | <b>(101)</b>                       | (5)                                | <b>(925)</b>                          |
| Loss on disaster                                                             |                                    | (22)                               |                                       |
| Business structure reform expenses (Note 5)                                  | <b>(4,504)</b>                     | (2,021)                            | <b>(41,115)</b>                       |
| Other—net                                                                    | <b>39</b>                          | 51                                 | <b>362</b>                            |
| Other income (expenses)—net                                                  | <b>36,269</b>                      | (1,921)                            | <b>331,050</b>                        |
| <b>INCOME BEFORE INCOME TAXES</b>                                            | <b>37,700</b>                      | 3,030                              | <b>344,109</b>                        |
| <b>INCOME TAXES (Note 9):</b>                                                |                                    |                                    |                                       |
| Current                                                                      | <b>10,007</b>                      | 1,329                              | <b>91,340</b>                         |
| Deferred                                                                     | <b>326</b>                         | 536                                | <b>2,976</b>                          |
| Total income taxes                                                           | <b>10,333</b>                      | 1,865                              | <b>94,316</b>                         |
| <b>NET INCOME</b>                                                            | <b>¥ 27,367</b>                    | ¥ 1,164                            | <b>\$ 249,792</b>                     |
|                                                                              |                                    | Yen                                | U.S. Dollars                          |
| <b>PER SHARE OF COMMON STOCK</b> (Note 2.r):                                 |                                    |                                    |                                       |
| Basic net income                                                             | <b>¥ 975.0</b>                     | ¥ 41.5                             | <b>\$ 8.90</b>                        |
| Diluted net income                                                           | —                                  | —                                  | —                                     |
| Cash dividends applicable to the period                                      | <b>48.0</b>                        | 48.0                               | <b>0.44</b>                           |

See notes to financial statements.

# Statement of Changes in Equity

Torii Pharmaceutical Co., Ltd.  
Year ended December 31, 2019

|                                      | Outstanding Number of Shares of Common Stock | Millions of Yen       |                            |                       |                                   |                            |                  |                                                         |                  |                 |
|--------------------------------------|----------------------------------------------|-----------------------|----------------------------|-----------------------|-----------------------------------|----------------------------|------------------|---------------------------------------------------------|------------------|-----------------|
|                                      |                                              | Common Stock (Note 7) | Capital Surplus (Note 7)   |                       |                                   | Retained Earnings (Note 7) |                  | Unrealized Gain (Loss) on Available-for-Sale Securities | Treasury Stock   | Total Equity    |
|                                      |                                              |                       | Additional Paid-in Capital | Other Capital Surplus | Stock Acquisition Rights (Note 7) | Legal Reserve              | Unappropriated   |                                                         |                  |                 |
| <b>BALANCE, DECEMBER 31, 2017</b>    | <b>28,048,397</b>                            | <b>¥ 5,190</b>        | <b>¥ 6,416</b>             |                       | <b>¥ 9</b>                        | <b>¥ 1,297</b>             | <b>¥ 74,940</b>  | <b>¥ 745</b>                                            | <b>¥ (1,480)</b> | <b>¥ 87,119</b> |
| Net income                           |                                              |                       |                            |                       |                                   |                            | 1,164            |                                                         |                  | 1,164           |
| Cash dividends paid, ¥48.0 per share |                                              |                       |                            |                       |                                   |                            | (1,346)          |                                                         |                  | (1,346)         |
| Repurchase of treasury stock         | (301)                                        |                       |                            |                       |                                   |                            |                  |                                                         | (0)              | (0)             |
| Disposal of treasury stock           | 13,058                                       |                       |                            | ¥ 10                  |                                   |                            |                  |                                                         | 25               | 35              |
| Net change in the year               |                                              |                       |                            |                       | 1                                 |                            |                  | 118                                                     |                  | 120             |
| <b>BALANCE, DECEMBER 31, 2018</b>    | <b>28,061,154</b>                            | <b>5,190</b>          | <b>6,416</b>               | <b>10</b>             | <b>11</b>                         | <b>1,297</b>               | <b>74,759</b>    | <b>864</b>                                              | <b>(1,455)</b>   | <b>87,092</b>   |
| Net income                           |                                              |                       |                            |                       |                                   |                            | 27,367           |                                                         |                  | 27,367          |
| Cash dividends paid, ¥48.0 per share |                                              |                       |                            |                       |                                   |                            | (1,347)          |                                                         |                  | (1,347)         |
| Repurchase of treasury stock         | (816)                                        |                       |                            |                       |                                   |                            |                  |                                                         | (1)              | (1)             |
| Disposal of treasury stock           | 12,701                                       |                       |                            | 2                     |                                   |                            |                  |                                                         | 25               | 27              |
| Net change in the year               |                                              |                       |                            |                       |                                   |                            |                  | (13)                                                    |                  | (13)            |
| <b>BALANCE, DECEMBER 31, 2019</b>    | <b>28,073,039</b>                            | <b>¥ 5,190</b>        | <b>¥ 6,416</b>             | <b>¥ 13</b>           | <b>¥ 11</b>                       | <b>¥ 1,297</b>             | <b>¥ 100,779</b> | <b>¥ 850</b>                                            | <b>¥ (1,431)</b> | <b>¥113,125</b> |

|                                       | Thousands of U.S. Dollars (Note 1) |                            |                       |                                   |                            |                   |                                                         |                    |                    |  |
|---------------------------------------|------------------------------------|----------------------------|-----------------------|-----------------------------------|----------------------------|-------------------|---------------------------------------------------------|--------------------|--------------------|--|
|                                       | Common Stock (Note 7)              | Capital Surplus (Note 7)   |                       |                                   | Retained Earnings (Note 7) |                   | Unrealized Gain (Loss) on Available-for-Sale Securities | Treasury Stock     | Total Equity       |  |
|                                       |                                    | Additional Paid-in Capital | Other Capital Surplus | Stock Acquisition Rights (Note 7) | Legal Reserve              | Unappropriated    |                                                         |                    |                    |  |
| <b>BALANCE, DECEMBER 31, 2018</b>     | <b>\$ 47,371</b>                   | <b>\$ 58,561</b>           | <b>\$ 93</b>          | <b>\$ 103</b>                     | <b>\$ 11,842</b>           | <b>\$ 682,356</b> | <b>\$ 7,886</b>                                         | <b>\$ (13,283)</b> | <b>\$ 794,932</b>  |  |
| Net income                            |                                    |                            |                       |                                   |                            | 249,792           |                                                         |                    | 249,792            |  |
| Cash dividends paid, \$0.43 per share |                                    |                            |                       |                                   |                            | (12,296)          |                                                         |                    | (12,296)           |  |
| Repurchase of treasury stock          |                                    |                            |                       |                                   |                            |                   |                                                         | (11)               | (11)               |  |
| Disposal of treasury stock            |                                    |                            | 27                    |                                   |                            |                   |                                                         | 228                | 255                |  |
| Net change in the year                |                                    |                            |                       |                                   |                            |                   | (125)                                                   |                    | (125)              |  |
| <b>BALANCE, DECEMBER 31, 2019</b>     | <b>\$ 47,371</b>                   | <b>\$ 58,561</b>           | <b>\$ 120</b>         | <b>\$ 103</b>                     | <b>\$ 11,842</b>           | <b>\$ 919,853</b> | <b>\$ 7,761</b>                                         | <b>\$ (13,066)</b> | <b>\$1,032,547</b> |  |

See notes to financial statements.



# Statement of Cash Flows

Torii Pharmaceutical Co., Ltd.  
Year ended December 31, 2019

|                                                             | Millions of Yen                    |                                    | Thousands of<br>U.S. Dollars (Note 1) |
|-------------------------------------------------------------|------------------------------------|------------------------------------|---------------------------------------|
|                                                             | Year Ended<br>December 31,<br>2019 | Year Ended<br>December 31,<br>2018 | Year Ended<br>December 31,<br>2019    |
| <b>OPERATING ACTIVITIES:</b>                                |                                    |                                    |                                       |
| Income before income taxes                                  | ¥ 37,700                           | ¥ 3,030                            | \$ 344,109                            |
| Adjustments for:                                            |                                    |                                    |                                       |
| Income taxes paid                                           | (1,401)                            | (1,855)                            | (12,793)                              |
| Depreciation and amortization                               | 985                                | 1,040                              | 8,999                                 |
| Business structure reform expenses                          | 4,504                              | 2,021                              | 41,115                                |
| Payments for Business structure reform expenses             | (4,373)                            |                                    | (39,918)                              |
| Gain on transfer of sales rights                            | (40,614)                           |                                    | (370,708)                             |
| The consideration of returning sales rights received        | 42,137                             |                                    | 384,603                               |
| Changes in assets and liabilities:                          |                                    |                                    |                                       |
| Increase in accrued consumption taxes                       | 2,885                              | 68                                 | 26,339                                |
| Decrease in trade notes and accounts receivable             | 1,983                              | 1,892                              | 18,101                                |
| Decrease in inventories                                     | 801                                | 1,811                              | 7,317                                 |
| Increase in trade accounts payable                          | (70)                               | (714)                              | (644)                                 |
| Other—net                                                   | (2,038)                            | 965                                | (18,610)                              |
| Total adjustments                                           | 4,798                              | 5,229                              | 43,801                                |
| Net cash provided by operating activities                   | 42,499                             | 8,259                              | 387,911                               |
| <b>INVESTING ACTIVITIES:</b>                                |                                    |                                    |                                       |
| Purchases of marketable securities                          | (31,713)                           | (25,710)                           | (289,459)                             |
| Proceeds from sale and redemption of marketable securities  | 44,300                             | 7,740                              | 404,344                               |
| Purchases of property, plant and equipment                  | (419)                              | (528)                              | (3,825)                               |
| Proceeds from sale of property, plant and equipment         | 1                                  | 0                                  | 10                                    |
| Purchases of investment securities                          | (11,853)                           | (8,448)                            | (108,191)                             |
| Proceeds from sale and redemption of investment securities  | 1,903                              |                                    | 17,377                                |
| Other—net                                                   | (119)                              | (122)                              | (1,094)                               |
| Net cash used in investing activities                       | 2,099                              | (27,068)                           | 19,161                                |
| <b>FINANCING ACTIVITIES:</b>                                |                                    |                                    |                                       |
| Repurchase of treasury stock                                | (1)                                | (0)                                | (11)                                  |
| Dividends paid                                              | (1,347)                            | (1,346)                            | (12,296)                              |
| Repayments of lease obligations                             | (85)                               | (85)                               | (778)                                 |
| Net cash used in financing activities                       | (1,433)                            | (1,432)                            | (13,086)                              |
| <b>NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS</b> | <b>43,165</b>                      | <b>(20,241)</b>                    | <b>393,986</b>                        |
| <b>CASH AND CASH EQUIVALENTS, BEGINNING OF YEAR</b>         | <b>15,654</b>                      | <b>35,895</b>                      | <b>142,882</b>                        |
| <b>CASH AND CASH EQUIVALENTS, END OF YEAR</b>               | <b>¥ 58,819</b>                    | <b>¥ 15,654</b>                    | <b>\$ 536,869</b>                     |

See notes to financial statements.

## 1 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 2018 financial statements to conform to the classifications used in 2019.

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 ¥109.56 to \$1, the approximate rate of exchange at December 31, 2019. Such translations should not be construed as representations that the Japanese yen 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.

## 2 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

**a. Nonconsolidation**—The Company has no subsidiaries as of December 31, 2019.

**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-than-temporary 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, 8 years for machinery and equipment, 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. Long-Lived Assets**—The Company reviews its long-lived assets for impairment whenever events or changes in circumstance indicate the carrying amount of an asset or asset group may not be recoverable. An impairment loss is recognized if the carrying amount of an asset or asset group exceeds the sum of the undiscounted future cash flows expected to result from the continued use and eventual disposition of the asset or asset group. The impairment loss would be measured as the amount by which the carrying amount of the asset exceeds its recoverable amount, which is the higher of the discounted cash flows from the continued use and eventual disposition of the asset or the

net selling price at disposition.

**g. Software**—Software is carried at cost less accumulated amortization, which is calculated by the straight-line method principally over 5 years.

**h. 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.

**i. 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 cost.

**j. 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.

**k. Research and Development Costs**—Research and development costs are charged to income as incurred.

**l. 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.

**m. 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.

**n. 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.

**o. Appropriations of Retained Earnings**—Appropriations of retained earnings are reflected in the financial statements for the following year upon the shareholders’ approval.

**p. 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.

**q. 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.

**r. 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 28,069,668 shares and 28,057,218 shares for the years ended December 31, 2019 and 2018, 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, 2019.

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.

**s. 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.

**t. New Accounting Pronouncements**—On March 30, 2018, the ASBJ issued ASBJ Statement No. 29, “Accounting Standard for Revenue Recognition” and ASBJ Guidance No. 30, “Implementation Guidance on Accounting Standard for Revenue Recognition.” The core principle of the standard and guidance is that an entity recognizes revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. An entity recognizes revenue in accordance with that core principle by applying the following steps:

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

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.

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.

**u. Change in Presentation Methods**—(Application of “Partial Amendments to Accounting Standard for Tax Effect Accounting”) On February 16, 2018, the ASBJ issued ASBJ Statement No. 28, “Partial Amendments to Accounting Standard for Tax Effect Accounting,” which requires deferred tax assets and deferred tax liabilities to be classified as investments and other assets and long-term liabilities, respectively. Deferred tax assets were previously classified as current assets and investments and other assets, and deferred tax liabilities were previously classified as current liabilities and long-term liabilities under the previous accounting standard. The revised accounting standard is effective for annual periods beginning on or after April 1, 2018. The Company retrospectively applied the revised accounting standard effective January 1, 2019, and deferred tax assets of 1,786 million and deferred tax liabilities of 292 million which were previously classified as current assets and current

liabilities, respectively, as of December 31, 2018, have been reclassified as investments and other assets in the accompanying balance sheet.

(Statement of Cash Flows) “Increase in accrued consumption taxes” included in “Other” in the statement of cash flows from operating activities for the fiscal year ended December 31, 2018 is separately presented from the fiscal year ended December 31, 2019

due to the increased quantitative materiality. As a result, ¥1,033 million for “Other,” which was shown in the statement of cash flows for the fiscal year ended December 31, 2018 is reclassified into ¥68 million in “Increase in accrued consumption taxes” and ¥965 million in “Other”.

### 3 MARKETABLE AND INVESTMENT SECURITIES

Marketable and investment securities as of December 31, 2019 and 2018, consisted of the following:

|                                  | Millions of Yen   |                   | Thousands of U.S. Dollars |
|----------------------------------|-------------------|-------------------|---------------------------|
|                                  | December 31, 2019 | December 31, 2018 | December 31, 2019         |
| Current:                         |                   |                   |                           |
| Government and corporate bonds   | ¥ 5,900           | ¥ 17,606          | \$ 53,859                 |
| Trust fund investments and other | 12,000            | 8,000             | 109,535                   |
| Total                            | ¥ 17,901          | ¥ 25,606          | \$ 163,394                |
| Noncurrent:                      |                   |                   |                           |
| Equity securities                | ¥ 1,513           | ¥ 1,703           | \$ 13,816                 |
| Government and corporate bonds   | 12,578            | 9,043             | 114,806                   |
| Trust fund investments and other | 5,672             | 3,024             | 51,776                    |
| Total                            | ¥ 19,764          | ¥ 13,770          | \$ 180,399                |

The costs and aggregate fair values of marketable and investment securities at December 31, 2019 and 2018, were as follows:

| December 31, 2019   | Millions of Yen |                  |                   | Fair Value |
|---------------------|-----------------|------------------|-------------------|------------|
|                     | Cost            | Unrealized Gains | Unrealized Losses |            |
| Available-for-sale: |                 |                  |                   |            |
| Equity securities   | ¥ 357           | ¥ 1,045          |                   | ¥ 1,403    |
| Debt securities     | 18,456          | 39               | ¥ 17              | 18,479     |
| Other               | 17,520          | 152              |                   | 17,673     |

| December 31, 2018   |                 |                  |                   |            |
|---------------------|-----------------|------------------|-------------------|------------|
| Available-for-sale: | Millions of Yen |                  |                   | Fair Value |
|                     | Cost            | Unrealized Gains | Unrealized Losses |            |
| Equity securities   | ¥ 357           | ¥ 1,235          |                   | ¥ 1,593    |
| Debt securities     | 26,668          | 8                | ¥ 27              | 26,649     |
| Other               | 11,000          | 24               |                   | 11,024     |

| December 31, 2019   | Thousands of U.S. Dollars |                  |                   | Fair Value |
|---------------------|---------------------------|------------------|-------------------|------------|
|                     | Cost                      | Unrealized Gains | Unrealized Losses |            |
| Available-for-sale: |                           |                  |                   |            |
| Equity securities   | \$ 3,266                  | \$ 9,546         |                   | \$ 12,812  |
| Debt securities     | 168,459                   | 364              | \$ 158            | 168,665    |
| Other               | 159,920                   | 1,391            |                   | 161,311    |

Available-for-sale securities whose fair value was not readily determinable as of December 31, 2019 and 2018, were as follows:

|                                               | Carrying Amount      |                      | Thousands of<br>U.S. Dollars |
|-----------------------------------------------|----------------------|----------------------|------------------------------|
|                                               | Millions of Yen      |                      |                              |
|                                               | December 31,<br>2019 | December 31,<br>2018 | December 31,<br>2019         |
| Available-for-sale—Unlisted equity securities | ¥ 110                | ¥ 110                | \$ 1,004                     |
| Total                                         | ¥ 110                | ¥ 110                | \$ 1,004                     |

## 4 INVENTORIES

Inventories at December 31, 2019 and 2018, consisted of the following:

|                                   | Millions of Yen      |                      | Thousands of<br>U.S. Dollars |
|-----------------------------------|----------------------|----------------------|------------------------------|
|                                   | December 31,<br>2019 | December 31,<br>2018 | December 31,<br>2019         |
| Finished products and merchandise | ¥ 4,090              | ¥ 4,722              | \$ 37,331                    |
| Work in process                   | 645                  | 626                  | 5,890                        |
| Raw materials and supplies        | 2,778                | 2,965                | 25,356                       |
| Total                             | ¥ 7,513              | ¥ 8,315              | \$ 68,578                    |

## 5 LONG-LIVED ASSETS

The Company reviewed its long-lived assets for impairment as of December 31, 2018. The Company grouped assets of the Sakura Plant and Institute from business-use assets to disposed assets and the carrying value of disposed assets for which profitability declined were written down to the recoverable amount. As a result, the Company recognized loss on impairment of fixed assets in the amount of ¥2,021 million. The components of the loss on impairment consisted of

buildings and structures of ¥1,417 million, machinery and equipment of ¥253 million, land of ¥234 million, and other property, plant and equipment of ¥114 million. The recoverable amount of that group was measured at its value in use and the discount rate used for computation of the present value of future cash flows was 6.57%.

No impairment loss was recognized in 2019.

## 6 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, 2019 and 2018, consisted of the following:



(1) The changes in defined benefit obligation for the years ended December 31, 2019 and 2018, were as follows:

|                                | Millions of Yen                    |                                    | Thousands of<br>U.S. Dollars       |
|--------------------------------|------------------------------------|------------------------------------|------------------------------------|
|                                | Year Ended<br>December 31,<br>2019 | Year Ended<br>December 31,<br>2018 | Year Ended<br>December 31,<br>2019 |
| Balance at beginning of period | ¥ 8,246                            | ¥ 8,237                            | \$ 75,271                          |
| Current service cost           | 463                                | 463                                | 4,233                              |
| Interest cost                  | 49                                 | 49                                 | 451                                |
| Actuarial (gains) losses       | (127)                              | 6                                  | (1,161)                            |
| Benefits paid                  | (1,872)                            | (509)                              | (17,093)                           |
| Balance at end of period       | ¥ 6,760                            | ¥ 8,246                            | \$ 61,701                          |

(2) The changes in plan assets for the years ended December 31, 2019 and 2018, were as follows:

|                                 | Millions of Yen                    |                                    | Thousands of<br>U.S. Dollars       |
|---------------------------------|------------------------------------|------------------------------------|------------------------------------|
|                                 | Year Ended<br>December 31,<br>2019 | Year Ended<br>December 31,<br>2018 | Year Ended<br>December 31,<br>2019 |
| Balance at beginning of period  | ¥ 7,170                            | ¥ 7,447                            | \$ 65,450                          |
| Expected return on plan assets  | 143                                | 148                                | 1,309                              |
| Actuarial gains (losses)        | 294                                | (313)                              | 2,688                              |
| Contributions from the employer | 320                                | 351                                | 2,927                              |
| Benefits paid                   | (1,846)                            | (463)                              | (16,853)                           |
| Balance at end of period        | ¥ 6,082                            | ¥ 7,170                            | \$ 55,521                          |

(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<br>U.S. Dollars |
|-------------------------------------------------------|----------------------|----------------------|------------------------------|
|                                                       | December 31,<br>2019 | December 31,<br>2018 | December 31,<br>2019         |
| Funded defined benefit obligation                     | ¥ 5,986              | ¥ 8,049              | \$ 54,638                    |
| Plan assets                                           | (6,082)              | (7,170)              | (55,521)                     |
|                                                       | (96)                 | 878                  | (883)                        |
| Unfunded defined benefit obligation                   | 773                  | 197                  | 7,063                        |
| Unrecognized actuarial losses                         | 473                  | 73                   | 4,317                        |
| Unrecognized prior service cost                       |                      | (72)                 |                              |
| Net liability arising from defined benefit obligation | ¥ 1,150              | ¥ 1,077              | \$ 10,497                    |

|                                                       | Millions of Yen      |                      | Thousands of<br>U.S. Dollars |
|-------------------------------------------------------|----------------------|----------------------|------------------------------|
|                                                       | December 31,<br>2019 | December 31,<br>2018 | December 31,<br>2019         |
| Liability for retirement benefits                     | ¥ 1,150              | ¥ 1,077              | \$ 10,497                    |
| Net liability arising from defined benefit obligation | ¥ 1,150              | ¥ 1,077              | \$ 10,497                    |

(4) The components of net periodic benefit costs for the years ended December 31, 2019 and 2018, were as follows:

|                                                                       | Millions of Yen                    |                                    | Thousands of<br>U.S. Dollars       |
|-----------------------------------------------------------------------|------------------------------------|------------------------------------|------------------------------------|
|                                                                       | Year Ended<br>December 31,<br>2019 | Year Ended<br>December 31,<br>2018 | Year Ended<br>December 31,<br>2019 |
| Service cost                                                          | ¥ 463                              | ¥ 463                              | \$ 4,233                           |
| Interest cost                                                         | 49                                 | 49                                 | 451                                |
| Expected return on plan assets                                        | (143)                              | (148)                              | (1,309)                            |
| Recognized actuarial (gains) losses                                   | (22)                               | 128                                | (207)                              |
| Amortization of prior service cost                                    | 72                                 | 87                                 | 662                                |
| Net periodic benefit costs                                            | ¥ 419                              | ¥ 579                              | \$ 3,830                           |
| The special severance benefit payment with the early retirement offer | ¥ 4,061                            |                                    | \$ 37,074                          |

Notes: The special severance benefit payment is recorded in “Business structure reform expenses.”

(5) Plan assets

a. Components of plan assets

Plan assets consisted of the following:

|                                             | December 31,<br>2019 | December 31,<br>2018 |
|---------------------------------------------|----------------------|----------------------|
| Debt investments                            | 45%                  | 52%                  |
| Equity investments                          | 25                   | 22                   |
| General account of life insurance companies | 9                    | 7                    |
| Others                                      | 21                   | 19                   |
| 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, 2019 and 2018, were set forth as follows:

|                                        | Year Ended<br>December 31,<br>2019 | Year Ended<br>December 31,<br>2018 |
|----------------------------------------|------------------------------------|------------------------------------|
| 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 ¥106 million (\$956 thousand) and ¥121 million are disclosed in cost of sales and selling, general and administrative expenses for the years ended December 31, 2019 and 2018 respectively, for which plan assets could not be allocated to each participating employer.

The “Tokyo Pharmaceutical Welfare Pension Fund.” which the Companies are joining received authorization from the Minister of Health, Labor and Welfare on April 1, 2018 for returning the contracted-out portion to the country (for the

past period), and has been transferred to the “Tokyo Pharmaceutical Company Pension Fund.”, which was established on April 1, 2018 as a successor system of “Tokyo Pharmaceutical Welfare Pension Fund.”

The funded status of the multiemployer pension plan at December 31, 2019 (based on information available as of March 31, 2019) and December 31, 2018 (based on information available as of March 31, 2018) to which contributions were recorded as net periodic retirement benefit costs, was as follows:

|                                                                            | Millions of Yen |                | Thousands of U.S. Dollars |
|----------------------------------------------------------------------------|-----------------|----------------|---------------------------|
|                                                                            | 2019            | March 31, 2018 | March 31, 2019            |
| Fair value of plan assets                                                  | ¥ 157,063       | ¥ 531,843      | \$ 1,433,585              |
| Sum of actuarial liabilities of pension plan and minimum actuarial reserve | 151,840         | 512,770        | 1,385,911                 |
| Difference                                                                 | ¥ 5,223         | ¥ 19,073       | \$ 47,674                 |

The Company's contribution percentage for the multiemployer pension plan at December 31, 2019 and 2018, was as follows:

|                         | December 31, 2019 | December 31, 2018 |
|-------------------------|-------------------|-------------------|
| Contribution percentage | 0.9%              | 1.4%              |

Notes (March 31, 2019):

1. The difference mainly resulted from prior service cost of ¥(13,593) million (\$124,076 thousand), deficiency brought forward of ¥(136,643) million (\$1,247,204 thousand) and special reserve fund of ¥155,460 million (\$1,418,954 thousand).
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 5 years and 5 months as of March 31, 2019.

Notes (March 31, 2018):

1. The difference mainly resulted from prior service cost of ¥(23,254) million, surplus brought forward of ¥11,381 million and special reserve fund of ¥30,947 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 15.5%. The remaining term of amortization is 4 years and 0 months as of March 31, 2018.

## 7

## 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 ¥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, 2019, are as follows:

| Stock Option      | Persons Granted                            | Number of Options Granted | Date of Grant | Exercise Price     | Exercise Period                        |
|-------------------|--------------------------------------------|---------------------------|---------------|--------------------|----------------------------------------|
| 2016 Stock Option | 6 Directors<br>6 Executive Vice Presidents | 28,000 shares             | 2016.4.8      | ¥ 2,736<br>(\$ 24) | From April 9, 2018<br>to April 8, 2021 |

The stock option activity is as follows:

|                                     | 2016 Stock<br>Option<br>(Shares) |
|-------------------------------------|----------------------------------|
| <b>Year Ended December 31, 2018</b> |                                  |
| <b>Non-vested</b>                   |                                  |
| December 31, 2017—Outstanding       | 26,400                           |
| Granted                             |                                  |
| Canceled                            |                                  |
| Vested                              | (26,400)                         |
| December 31, 2018—Outstanding       |                                  |
| <b>Vested</b>                       |                                  |
| December 31, 2017—Outstanding       |                                  |
| Vested                              | 26,400                           |
| Exercised                           |                                  |
| Canceled                            |                                  |
| December 31, 2018—Outstanding       | 26,400                           |
| <b>Year Ended December 31, 2019</b> |                                  |
| <b>Non-vested</b>                   |                                  |
| December 31, 2018—Outstanding       |                                  |
| Granted                             |                                  |
| Canceled                            |                                  |
| Vested                              |                                  |
| December 31, 2019—Outstanding       |                                  |
| <b>Vested</b>                       |                                  |
| December 31, 2018—Outstanding       | 26,400                           |
| Vested                              |                                  |
| Exercised                           |                                  |
| Canceled                            |                                  |
| December 31, 2019—Outstanding       | 26,400                           |
| Exercise price                      | ¥ 2,736<br>(\$ 24)               |
| Average stock price at exercise     |                                  |
| Fair value price at grant date      | ¥ 427.70<br>(\$ 3.90)            |

## 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, 2019 and 2018, respectively.

The tax effects of significant temporary differences, which resulted in deferred tax assets and liabilities at December 31, 2019 and 2018, are as follows:

|                                                  | Millions of Yen      |                      | Thousands of<br>U.S. Dollars |
|--------------------------------------------------|----------------------|----------------------|------------------------------|
|                                                  | December 31,<br>2019 | December 31,<br>2018 | December 31,<br>2019         |
| Deferred tax assets:                             |                      |                      |                              |
| Impairment loss                                  | ¥ 618                | ¥ 640                | \$ 5,646                     |
| Accrued enterprise taxes                         | 511                  | 68                   | 4,672                        |
| Liabilities for retirement benefits              | 351                  | 329                  | 3,212                        |
| Prepayment of research and development costs     | 162                  | 1,173                | 1,486                        |
| Accrued bonuses to employees                     | 150                  | 206                  | 1,377                        |
| Loss on valuation of inventories                 | 89                   | 142                  | 819                          |
| Other                                            | 346                  | 412                  | 3,162                        |
| Less valuation allowance                         | (687)                | (1,098)              | (6,278)                      |
| Total                                            | 1,544                | 1,875                | 14,098                       |
| Deferred tax liabilities:                        |                      |                      |                              |
| Unrealized gain on available-for-sale securities | 370                  | 376                  | 3,382                        |
| Other                                            | —                    | 4                    | —                            |
| Total                                            | 370                  | 381                  | 3,382                        |
| Net deferred tax assets                          | ¥ 1,174              | ¥ 1,494              | \$ 10,716                    |

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, 2019, with the corresponding figures for 2018, is as follows:

|                                                    | Year Ended<br>December 31,<br>2019 | Year Ended<br>December 31,<br>2018 |
|----------------------------------------------------|------------------------------------|------------------------------------|
| Normal effective statutory tax rate                | 30.6%                              | 30.9%                              |
| Expenses not deductible for income tax purposes    | 0.1                                | 2.5                                |
| Dividend income deductible for income tax purposes | (0.0)                              | (0.0)                              |
| Per capita levy                                    | 0.2                                | 2.3                                |
| Tax credits                                        | (2.2)                              | (9.4)                              |
| Increase in valuation allowance                    | (1.1)                              | 36.3                               |
| Other—net                                          | (0.2)                              | (0.9)                              |
| Actual effective tax rate                          | 27.4%                              | 61.6%                              |

## 10 RESEARCH AND DEVELOPMENT COSTS

Research and development costs charged to income were ¥2,956 million (\$26,989 thousand) and ¥4,138 million for the years ended December 31, 2019 and 2018, 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, 2019 and 2018, were ¥707 million (\$6,455 thousand) and ¥1,368 million, respectively.

The minimum rental commitments under non-cancelable operating leases were as follows:

|                     | Millions of Yen  | Thousands of U.S. Dollars |
|---------------------|------------------|---------------------------|
|                     | 2019             | 2019                      |
|                     | Operating Leases | Operating Leases          |
| Due within one year | ¥ 61             | \$ 565                    |
| Due after one year  | 105              | 962                       |
| Total               | ¥ 167            | \$ 1,527                  |

## 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 |            |                      |
|--------------------------------------------------------------------|-----------------|------------|----------------------|
|                                                                    | Carrying Amount | Fair Value | Unrealized Gain/Loss |
| <b>December 31, 2019</b>                                           |                 |            |                      |
| Cash and cash equivalents                                          | ¥ 58,819        | ¥ 58,819   |                      |
| Receivables:                                                       |                 |            |                      |
| Trade accounts                                                     | 25,096          | 25,096     |                      |
| Parent                                                             | 137             | 137        |                      |
| Marketable and investment securities—Available-for-sale securities | 37,556          | 37,556     |                      |
| Total                                                              | ¥ 121,610       | ¥ 121,610  |                      |
| Payables:                                                          |                 |            |                      |
| Trade accounts                                                     | ¥ 3,862         | ¥ 3,862    |                      |
| Parent                                                             | 2,155           | 2,155      |                      |
| Other                                                              | 4,282           | 4,282      |                      |
| Income taxes payable                                               | 9,836           | 9,836      |                      |
| Total                                                              | ¥ 20,137        | ¥ 20,137   |                      |
| <br>                                                               |                 |            |                      |
| December 31, 2018                                                  |                 |            |                      |
| Cash and cash equivalents                                          | ¥ 15,654        | ¥ 15,654   |                      |
| Receivables:                                                       |                 |            |                      |
| Trade accounts                                                     | 27,094          | 27,094     |                      |
| Parent                                                             | 975             | 975        |                      |
| Marketable and investment securities—Available-for-sale securities | 39,267          | 39,267     |                      |
| Total                                                              | ¥ 82,991        | ¥ 82,991   |                      |
| Payables:                                                          |                 |            |                      |
| Trade accounts                                                     | ¥ 3,714         | ¥ 3,714    |                      |
| Parent                                                             | 3,441           | 3,441      |                      |
| Other                                                              | 3,579           | 3,579      |                      |
| Income taxes payable                                               | 852             | 852        |                      |
| Total                                                              | ¥ 11,587        | ¥ 11,587   |                      |

|                                                                    | Thousands of U.S. Dollars |              |                      |
|--------------------------------------------------------------------|---------------------------|--------------|----------------------|
|                                                                    | Carrying Amount           | Fair Value   | Unrealized Gain/Loss |
| <b>December 31, 2019</b>                                           |                           |              |                      |
| Cash and cash equivalents                                          | \$ 536,867                | \$ 536,867   |                      |
| Receivables:                                                       |                           |              |                      |
| Trade accounts                                                     | 229,069                   | 229,069      |                      |
| Parent                                                             | 1,259                     | 1,259        |                      |
| Marketable and investment securities—Available-for-sale securities | 342,790                   | 342,790      |                      |
| Total                                                              | \$ 1,109,987              | \$ 1,109,987 |                      |
| Payables:                                                          |                           |              |                      |
| Trade accounts                                                     | \$ 35,257                 | \$ 35,257    |                      |
| Parent                                                             | 19,675                    | 19,675       |                      |
| Other                                                              | 39,088                    | 39,088       |                      |
| Income taxes payable                                               | 89,777                    | 89,777       |                      |
| Total                                                              | \$ 183,799                | \$ 183,799   |                      |

#### 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 of Yen   |                   | Thousands of U.S. Dollars |
|                 | December 31, 2019 | December 31, 2018 | December 31, 2019         |
| Unlisted shares | ¥ 110             | ¥ 110             | \$ 1,004                  |

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       |                                  |                                    |
|------------------------------------------------------------------------------------------------|-----------------------|----------------------------------|------------------------------------|
|                                                                                                | Due in 1 Year or Less | Due after 1 Year through 5 Years | Due after 5 Years through 10 Years |
| <b>December 31, 2019</b>                                                                       |                       |                                  |                                    |
| Cash and cash equivalents                                                                      | ¥ 58,819              |                                  |                                    |
| Receivables:                                                                                   |                       |                                  |                                    |
| Trade accounts                                                                                 | 25,096                |                                  |                                    |
| Parent                                                                                         | 137                   |                                  |                                    |
| Marketable and investment securities—Available-for-sale securities with contractual maturities | 17,901                | ¥ 9,894                          | ¥ 5,835                            |
| Total                                                                                          | ¥ 101,955             | ¥ 9,894                          | ¥ 5,835                            |

| December 31, 2018                                                                              | Millions of Yen          |                                     |                                       |
|------------------------------------------------------------------------------------------------|--------------------------|-------------------------------------|---------------------------------------|
|                                                                                                | Due in<br>1 Year or Less | Due after 1 Year<br>through 5 Years | Due after 5 Years<br>through 10 Years |
| Cash and cash equivalents                                                                      | ¥ 15,653                 |                                     |                                       |
| Receivables:                                                                                   |                          |                                     |                                       |
| Trade accounts                                                                                 | 27,094                   |                                     |                                       |
| Parent                                                                                         | 975                      |                                     |                                       |
| Marketable and investment securities—Available-for-sale securities with contractual maturities | 25,606                   | ¥ 4,450                             | ¥ 7,617                               |
| Total                                                                                          | ¥ 69,330                 | ¥ 4,450                             | ¥ 7,617                               |

| December 31, 2019                                                                              | Thousands of U.S. Dollars |                                     |                                       |
|------------------------------------------------------------------------------------------------|---------------------------|-------------------------------------|---------------------------------------|
|                                                                                                | Due in<br>1 Year or Less  | Due after 1 Year<br>through 5 Years | Due after 5 Years<br>through 10 Years |
| Cash and cash equivalents                                                                      | \$ 536,866                |                                     |                                       |
| Receivables:                                                                                   |                           |                                     |                                       |
| Trade accounts                                                                                 | 229,069                   |                                     |                                       |
| Parent                                                                                         | 1,259                     |                                     |                                       |
| Marketable and investment securities—Available-for-sale securities with contractual maturities | 163,394                   | \$ 90,310                           | \$ 53,262                             |
| Total                                                                                          | \$ 930,589                | \$ 90,310                           | \$ 53,262                             |

## 13 RELATED PARTY TRANSACTIONS

Transactions of the Company with the parent company for the years ended December 31, 2019 and 2018, were as follows:

|                                             | Millions of Yen                    |                                    | Thousands of<br>U.S. Dollars       |
|---------------------------------------------|------------------------------------|------------------------------------|------------------------------------|
|                                             | Year Ended<br>December 31,<br>2019 | Year Ended<br>December 31,<br>2018 | Year Ended<br>December 31,<br>2019 |
| Purchases                                   | ¥ 20,097                           | ¥ 12,412                           | \$ 183,437                         |
| The consideration of returning sales rights | 42,137                             |                                    | 384,602                            |
| Forward exchange contracts                  | 4,236                              |                                    | 38,663                             |

The balances due to or from the parent company at December 31, 2019 and 2018, were as follows:

|                                                | Millions of Yen      |                      | Thousands of<br>U.S. Dollars |
|------------------------------------------------|----------------------|----------------------|------------------------------|
|                                                | December 31,<br>2019 | December 31,<br>2018 | December 31,<br>2019         |
| Deposits included in cash and cash equivalents | ¥ 37,796             | ¥ 9,169              | \$ 344,980                   |
| Trade accounts payable                         | 1,890                | 2,942                | 17,251                       |

## 14 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, 2019 and 2018.

Sales to major customers were as follows:

| Name of Customer              | Millions of Yen              |                              | Thousands of U.S. Dollars    |
|-------------------------------|------------------------------|------------------------------|------------------------------|
|                               | Year Ended December 31, 2019 | Year Ended December 31, 2018 | Year Ended December 31, 2019 |
| Alfresa Corporation           | ¥ 9,048                      | ¥ 14,511                     | \$ 82,591                    |
| Mediceo Corporation           | 8,510                        | 15,371                       | 77,677                       |
| Suzuken Co., Ltd.             | 8,413                        | 13,128                       | 76,797                       |
| Toho Pharmaceutical Co., Ltd. | 4,781                        | 6,785                        | 43,644                       |

## 15 SUBSEQUENT EVENTS

### *Transfer of Sakura Plant*

At the meeting of the Board of Directors held on March 18, 2020, it was decided and signed the agreement that the company would transfer its Sakura Plant in Sakura, Chiba, to IWAKI SEIYAKU CO., LTD. (“IWAKI”).

#### 1. Purpose of the transfer

The company has concluded that it would be best to transfer the Sakura Plant to IWAKI. Since the profitability of long term listed drugs has decreased following a drastic reform of the drug pricing system, the company has considered the possibility of a gradual transfer of the manufacture of pharmaceutical products to other companies, or of switching to contract manufacturing, as part of the business structure reform named “Medium-Term Management Plan 2021. Employment of the current Sakura Plant workforce will be

maintained under IWAKI. A stable supply of the company’s products will continue to be manufactured in the Sakura Plant. The company believes that the quality assurance system and technological capabilities that have been established within the Sakura Plant will continue under IWAKI’s stewardship, maintaining stable supply.

#### 2. Transfer method and target

A wholly-owned subsidiary will be founded by the company (“Sakura New Company”), followed by a transfer of the Sakura Plant’s assets to Sakura New Company via a company spin-off on July 1, 2020 (scheduled), resulting in a transfer of all the shares of Sakura New Company from the company to IWAKI on the same day. Furthermore, Torii will outsource production of the Sakura Plant’s existing line of products to Sakura New Company after the Share Transfer.

### 3. Summary of the Company Where Shares Are to Be Transferred to

|                                          |                                                                                                                                                                                                                                        |
|------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Name                                     | IWAKI SEIYAKU CO., LTD.                                                                                                                                                                                                                |
| Location                                 | 4-8-2 Nihonbashi-honcho, Chuo-ku, Tokyo, Japan                                                                                                                                                                                         |
| Capital                                  | ¥210 million                                                                                                                                                                                                                           |
| Title and name of the representative     | Yoshiyuki Nishikubo (President)                                                                                                                                                                                                        |
| Total equity<br>(As of November 30,2019) | ¥6,116 million                                                                                                                                                                                                                         |
| Total assets<br>(As of November 30,2019) | ¥10,627 million                                                                                                                                                                                                                        |
| Business contents                        | Manufacturing and selling of ethical drugs, OTC drugs, animal drugs, APIs, pharmaceutical intermediates, food additives, cosmetic materials, chemicals for materials for recording information, and intermediates of dyes and pigments |

### 4. Value of Share Transfer

Consideration for the transfer of all shares of Sakura New Company from IWAKI to the company is expected to be ¥1.1 billion. In addition, the net assets of the Sakura Plant to be split (the book value as of the end of December 2019) are

about approximately ¥1.5 billion. Net assets will be finalized after adding and subtracting the above amount, considering the fluctuation which may occur by the day before the effective date of the company spin-off.

### 5. Schedule

|                                                                         |                          |
|-------------------------------------------------------------------------|--------------------------|
| Establishment of Sakura New Company                                     | April 2020 (scheduled)   |
| Date of the Company Spin-Off Agreement                                  | May 2020 (scheduled)     |
| Date of the Company Spin-Off (Effective Date)<br>Date of Share Transfer | July 1, 2020 (scheduled) |

### 6. Impact on Financial Performance

The gain or loss on the transfer of the shares is scheduled to be recorded in the fiscal year 2020. The gain or loss on the transfer is currently unknown.

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## INDEPENDENT AUDITOR'S REPORT

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

We have audited the accompanying balance sheet of Torii Pharmaceutical Co., Ltd. as of December 31, 2019, and the related statements of income, changes in equity, and cash flows for the year then ended, and a summary of significant accounting policies and other explanatory information, all expressed in Japanese yen.

### Management's Responsibility for the Financial Statements

Management is responsible for the preparation and fair presentation of these 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.

### Auditor's Responsibility

Our responsibility is to express an opinion on these financial statements based on our audit. We conducted our audit in accordance with auditing standards generally accepted in Japan. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free from material misstatement.

An audit involves performing procedures to obtain audit evidence about the amounts and disclosures in the financial statements. The procedures selected depend on the auditor's judgment, including the assessment of the risks of material misstatement of the financial statements, whether due to fraud or error. In making those risk assessments, the auditor considers internal control relevant to the entity's preparation and fair presentation of the financial statements 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 entity's internal control. An audit also includes evaluating the appropriateness of accounting policies used and the reasonableness of accounting estimates made by management, as well as evaluating the overall presentation of the financial statements.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our audit opinion.

### Opinion

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Torii Pharmaceutical Co., Ltd. as of December 31, 2019, and the results of its operations 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.

*Deloitte Touche Tohmatsu LLC*

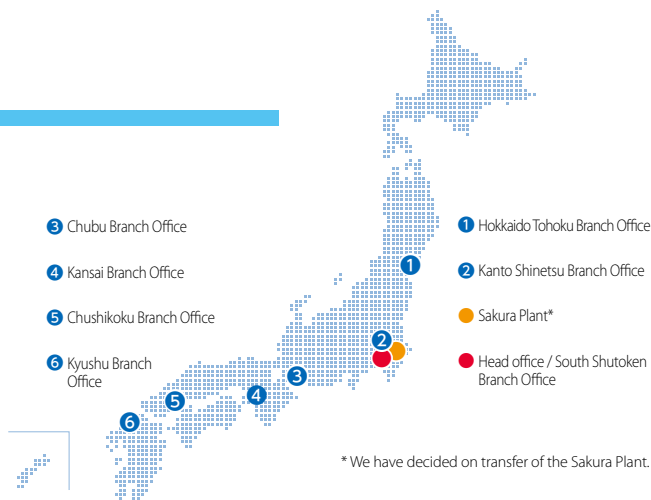
March 25, 2020



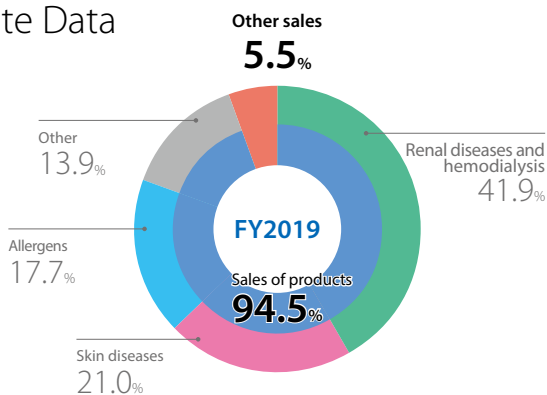
# Corporate Information

## Corporate Overview

**Corporate name** Torii Pharmaceutical Co., Ltd.  
**Established** November 1, 1921  
**Paid-in capital** ¥5,190 million  
**Business lines** Manufacturing and marketing of pharmaceutical products  
**Number of employees** 660  
**Stock exchange listing** The first section 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



## Corporate Data



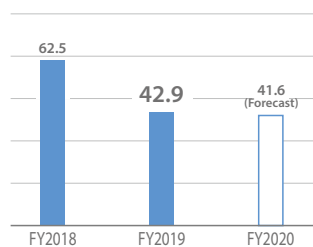
### Net sales by disease area

(Millions of Yen)

|                                 | FY2018        | FY2019        |
|---------------------------------|---------------|---------------|
| <b>Net sales</b>                | <b>62,551</b> | <b>42,998</b> |
| Sales of products               | 61,835        | 40,641        |
| Renal diseases and hemodialysis | 21,991        | 18,005        |
| Skin diseases                   | 9,126         | 9,049         |
| Allergens                       | 3,803         | 7,627         |
| Other                           | 5,464         | 5,959         |
| HIV diseases                    | 21,448        | —             |
| Other sales                     | 716           | 2,356         |

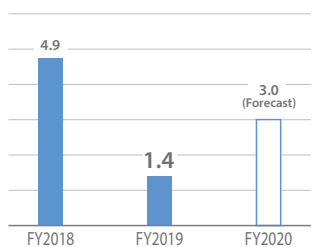
### Net Sales

(Billions of Yen)



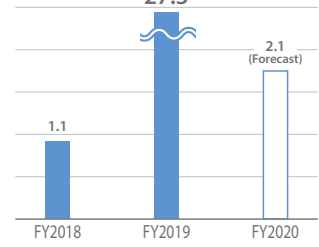
### Operating Income

(Billions of Yen)



### Net Income

(Billions of Yen)



## Mainstay Products

### 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.

### Riona Tablets Therapeutic agent for hyperphosphatemia



Riona is a medication which treats hyperphosphatemia in patients with chronic kidney disease, including hemodialysis, peritoneal dialysis, and non-dialysis chronic kidney disease patients, by suppressing phosphate absorption into the body.

### ANTEBATE Topical corticosteroid



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

### CEDARCURE Japanese Cedar Pollen Sublingual Tablets Japanese cedar pollinosis (Allergen Immunotherapy)



CEDARCURE is a sublingual allergen immunotherapy drug for Japanese cedar pollinosis. This fast-dissolving sublingual tablet was first available in Japan for adult and pediatric patients.

### MITICURE House Dust Mite Sublingual Tablets House dust mite allergy (Allergen Immunotherapy)



MITICURE is an allergen immunotherapy tablet for house dust mite-induced allergic rhinitis. This drug was approved an additional dosage and administration for pediatric indication in February 2018.

### CEDARTOLEN SUBLINGUAL DROP—Japanese Cedar Pollen Japanese cedar pollinosis (Allergen Immunotherapy)



CEDARTOLEN is Japan's first sublingually-administered allergen immunotherapy for Japanese cedar pollinosis. It is used for the treatment through acclimating the body to allergens by administering the product to help alleviate allergy symptoms.



TORII PHARMACEUTICAL CO., LTD.

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