# Annual Report 2017

For the year endea December 31, 2017



# Corporate Mission

#### The Corporate Mission of Torii

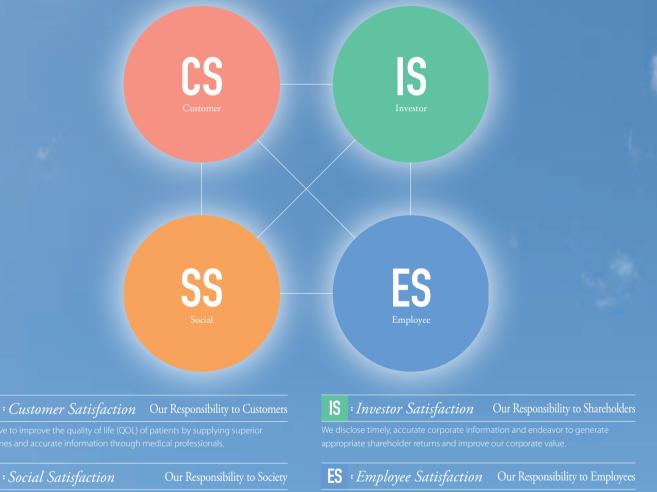
Torii Pharmaceutical Co., Ltd. (hereinafter "Torii") aims to contribute to the improvement of human health and to fulfill its responsibilities to customers, shareholders, society and employees, by supplying world-class pharmaceutical products.

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.

# 4S MODEL

Note) 4S is the collective term for CS, IS, SS, and ES.



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

SS

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.

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# Top Message

Torii Pharmaceutical Co., Ltd., based on its 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," formulated its "medium-term management plan 2018" that covers the three-year period from fiscal 2016 to fiscal 2018 in order to achieve sustainable business growth and medium- to long-term improvement in corporate value. We have focused our management resources in four priority areas, "renal diseases and emodialysis," "skin diseases," "allergens," and "HIV infection," and worked on priority issues as follows.

- "(1) Carrying out active business investments aiming for medium- to long-term growth"
- "(2) Focusing on promoting development as well as maximizing values of mainstay products in each priority area"
- "(3) Improving and reinforcing business structure for sustainable growth"
- "(4) Earning and maintaining the trust of stakeholders"

We will continue to further accelerate and strengthen our efforts, based on the drastic reform of the drug price system in April 2018, to respond to the changes in our increasingly challenging business environment.

We will continue to make a concerted effort to achieve sustainable growth going forward in fiscal 2018, and will do our utmost to remain a pharmaceutical company that contributes to

people's health. We would greatly appreciate your further support and cooperation.



Shoichiro Takagi

Representative Director, President and Chief Executive Officer

# Progress of the "Medium-term Management Plan 2018 (Fiscal 2016-Fiscal 2018)"

In order to overcome changes in the increasingly challenging business environment and achieve sustainable business growth and medium- to long-term improvement in corporate value, the Company has formulated its "medium-term management plan 2018" (announced in February 2016) that covers the three-year period from fiscal 2016 to fiscal 2018, and has engaged in initiatives for the four key issues.

In fiscal 2017, the second year under this medium-term management plan, we steadily implemented the plan as follows: "(1) Carrying out active business investments aiming for medium-

## to long-term growth"

We further reinforced and promoted our exploration and in-license activities, working to acquire in-licensed drugs (including alliances) with the potential to become future mainstay products. The major achievement of these efforts was the conclusion in October 2017 of a contract regarding the domestic co-development and commercialization of JTZ-951, an oral HIF-PH inhibitor indicated for renal anemia in clinical development in Japan by Japan Tobacco Inc. (hereinafter "JT").

JT has 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 once it is approved. "(2) Focusing on promoting development as well as maximizing values of mainstay products in each priority area"

In order to maximize the value of mainstay products in each priority area, Torii actively promoted joint development with JT of in-licensed drugs already acquired.

In addition to working to increase market penetration and

expansion of "Riona Tablets", "CEDARTOLEN SUBLINGUAL DROP - Japanese Cedar Pollen", "MITICURE House Dust Mite Sublingual Tablets", "Genvoya Combination Tablets", and "Descovy Combination Tablets", we also focused on the prompt market penetration for orally disintegrating tablet, REMITCH, as a new dosage form, which were launched in June 2017, and for which an additional indication of "improving pruritus in peritoneal dialysis patients (use only when sufficient efficacy is not obtained with the existing therapies or treatments)" received approval. We also promoted development, such as co-developing JAK inhibitor, JTE-052 (for topical use in dermatological indications) together with JT. In January 2018, we received initial results from a comparative study performed as part of domestic Phase III clinical trials for atopic dermatitis patients.

# "(3) Improving and reinforcing business structure for sustainable growth"

In addition to promotion of company-wide initiatives aimed at improving productivity, we also further strengthened interorganizational coordination and further promoted collaboration and coordination with outside partners such as JT.

"(4) Earning and maintaining the trust of stakeholders"

In order to further enforce compliance, we continuously conducted educational and awareness-raising activities such as study groups in all divisions. We also appropriately implemented measures and information disclosure based on the Corporate Governance Policy formulated in fiscal 2016.

#### Financial Forecasts for the FY2018

	FY2017 (Billions of Yen)	FY2018 forecast (Billions of Yen)	Change (Billions of Yen)
Net sales	64.1	60.7	(3.4)
Operating income	6.2	3.5	(2.7)
Ordinary income	6.4	3.6	(2.8)
Net income	4.7	2.6	(2.1)

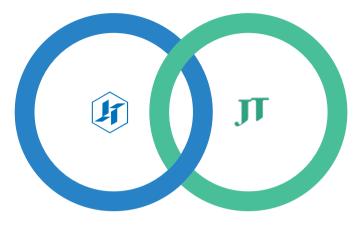
# Medium-term Management Plan 2018 Targets

Under the medium-term management plan 2018, we set fiscal year 2018 management targets of ¥62.0 billion in net sales and ¥8.0 billion in operating income (before deduction of research and development costs). However, our fiscal 2018 financial forecast is for net sales of ¥60.7 billion and operating income (before deduction of research and development costs) of ¥8.2 billion. Although there were differences in product structure forecasts, the primary reason for this gap between the net sales target and net sales forecast was the effect of the drastic reform of the drug pricing system, which was not anticipated when the mediumterm management plan was formulated.

# Summary of Business

# Collaboration with Japan Tobacco Inc.(JT)

In the pharmaceutical industry, the technology required to develop new drugs is becoming increasingly sophisticated, and R&D costs are generally rising. At the same time, the requirements for new drug approval are becoming ever more demanding. As a result, it often takes many years to release a new product to market. In keeping with our tradition of always seeking and maximizing synergies, built over a corporate history dating back more than 130 years, Torii joined the JT Group in 1998. In 1999, we established a business collaboration with JT, which envisioned R&D oriented pharmaceutical activities. In this new partnership, R&D for new drugs came under the control of JT, while Torii took over sales and marketing functions. In April 2006, Torii also extended its manufacturing operations to include those of JT. This partnership has enabled JT and Torii to continuously supply high-quality pharmaceutical products.



# Sales and Marketing

Torii has about 500 medical representatives (MRs) working at 14 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. Key products manufactured at this GMP\*-certified plant include the protease inhibitor FUTHAN for injection, the topical corticosteroid ANTEBATE OINTMENT and ANTEBATE CREAM, and the uricosuric agent URINORM Tab. 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 14001certification of the Sakura Plant.

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

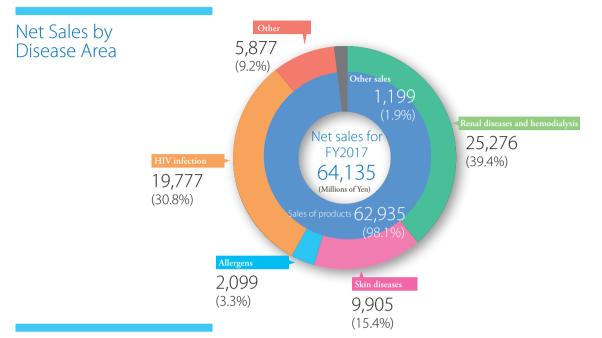
# Research and Development

JT aims to build up a unique, world-class pharmaceutical business driven by R&D, and to increase our market presence through original and innovative drugs, implementing efforts in research and development that will allow us to merit the respect and appreciation of patients and medical staff around the world.

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

As a result of the division of R&D functions between Torii Pharmaceutical and JT, JT is now responsible for R&D activities pertaining to new compounds, while Torii is responsible primarily for improvements to the formulations of existing products, and the development of additional indications. Torii also carries out its own R&D in its specific areas of expertise.





# Net Sales by Product

				(Millions of Yen
Brand name	Area	Therapeutic indication	FY2016	FY2017
REMITCH	Renal diseases and Hemodialysis	Oral antipruritic agent	13,645	13,838
Descovy*3	HIV infection	Antiviral agent for HIV	_	9,218
Genvoya*2	HIV infection	Antiviral agent for HIV	1,865	6,325
ANTEBATE*1	Skin diseases	Topical corticosteroid	6,277	6,282
Riona	Renal diseases and Hemodialysis	Agent for hyperphosphatemia	5,634	6,245
Truvada	HIV infection	Antiviral agent for HIV	12,754	3,941
BIO-THREE	Other	Viable bacterial preparations	2,455	2,545
KAYEXALATE <sup>*1</sup>	Renal diseases and Hemodialysis	Agent for hyperkalemia	2,178	2,123
FUTHAN*1	Renal diseases and Hemodialysis	Protease inhibitor	2,462	2,047
ZEFNART	Skin diseases	Topical antifungal agent	1,275	1,483
LOCOID*1	Skin diseases	Topical corticosteroid	1,352	1,411
CEDARTOLEN*1	Allergens	Japanese cedar pollinosis (Allergen Immunotherapy)	937	1,295
Magsent	Other	Tocolysis in threatened premature labor/Eclampsia-suppressing and treatment	1,165	1,115
URINORM*1	Renal diseases and Hemodialysis	Uricosuric agent	1,219	1,020
Stribild	HIV infection	Antiviral agent for HIV	2,371	148
Others			4,023	3,891

\*1 In-house products \*2 Launched in July 2016 \*3 Launched in January 2017



# Research and Development

Torii divides its research and development functions of pharmaceutical business between itself and its parent company, JT. JT is responsible for research and development activities pertaining to new compounds, whereas Torii is responsible for improvements to the formulations of existing products and the development of additional indications. Torii also carries out its own research and development in its specific areas of expertise. Moreover, Torii collaborates with JT to search and develop candidates for new in-licensed drugs.

Below are some of the major achievements of our in-licensing and research and (joint) development activities (as of April 26, 2018).

#### (Renal diseases and hemodialysis)

- In March 2017, Toray Industries, Inc. (hereinafter "Toray") received manufacturing and marketing approval for orally disintegrating tablet, REMITCH (partner: JT) as a new formulation, for which Toray has already received manufacturing and marketing approval and which are promoted and distributed by Torii in Japan. Furthermore, in September 2017, Toray received approval for partial changes in manufacturing and marketing approval matters regarding an additional indication for improving pruritus in peritoneal dialysis patients in Japan (use only when sufficient efficacy is not obtained with the existing therapies or treatments) for REMITCH.
- In October 2017, Torii and JT concluded an agreement for the domestic co-development and commercialization of JTZ-951, an oral HIF-PH inhibitor indicated for renal anemia being clinically developed by JT in Japan, and began a domestic Phase III clinical trial. This drug will be developed jointly by JT and Torii, and will be marketed by Torii.

#### (Skin diseases)

A domestic Phase III clinical trial for adults and a domestic Phase II clinical trial for children have been conducted for JTE-052, a JAK inhibitor for topical use in dermatological indications being developed jointly by JT and Torii in Japan. In January 2018, we already received the top-line results of Phase 3 comparative study. In the top-line results, the primary endpoint of efficacy has met superiority to placebo.

Furthermore, there were no clinically significant findings on safety and tolerability of JTE-052 ointment within the treatment period.

 It has been decided to terminate a domestic Phase II clinical trial currently in progress for serlopitant. Serlopitant (development code: JTS-661) is a neurokinin (NK-1) receptor antagonist being developed jointly by Torii and JT after signing a license agreement with Menlo Therapeutics Inc. for the exclusive rights to develop and commercialize serlopitant in Japan.

We are currently considering whether or not to continue domestic development of this drug.

#### (Allergens)

- In March 2017, we filed an application for additional approval of dosage and administration for children for MITICURE House Dust Mite Sublingual Tablets (Allergen Immunotherapy) (development code: TO-203) being distributed in Japan by Torii. This application was approved in February 2018.
- In September 2017, we received approval for the domestic manufacturing and marketing of CEDARCURE Japanese Cedar Pollen Sublingual Tablets (development code: TO-206), a Japanese cedar pollinosis immunotherapy drug. In April 2018, the drug was listed on the National Health Insurance drug price list. This product is scheduled for launch in late June 2018.



# Mainstay research and development products (As of April 26, 2018)

Development code	Indication	Formulation/ Route of		Development stage (domestic)			Domotic	
CODE [Product Name]	Indication	administration	Phase I	Phase II	Phase III	Application	Approval	Remarks
Renal disease	Renal diseases and hemodialysis							
<b>JTT-751</b> [Riona® Tablets]	Iron-deficiency anemia	Oral		Phase II	- - - - - - - - - - - - - - - - - - -			<ul> <li>Licensing agreement signed with Keryx for development and commercialization of hyperphosphatemia drug in Japan</li> <li>Co-development with JT</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>
JTZ-951	Anemia associated with chronic kidney disease	Oral			Phase III			<ul> <li>JT's original compound</li> <li>Licensing agreement signed with JT for development and commercialization in Japan</li> </ul>
Skin diseases					•	•	9 0 0 0 0	
	Atopic dermatitis	Topical			Phase III			<ul> <li>JT's original compound</li> <li>Licensing agreement signed with JT for development and commercialization in Japan</li> </ul>
JTE-052	Atopic dermatitis in children	Topical		Phase II	4 4 4 4 4 4 4 4 4 4 4 4 4 4			<ul> <li>JT's original compound</li> <li>Licensing agreement signed with JT for development and commercialization in Japan</li> </ul>
JTS-661	Pruritus	Oral		Phase II*	• • • • • • • • • • • • • • • • • • •			<ul> <li>Licensing agreement signed with Menlo Therapeutics Inc. for development and commercialization in Japan</li> <li>Co-development with JT</li> <li>Phase II study discontinued :Examining the future development policy</li> </ul>
Allergens			•		• • •	•	0 0 0 0	
TO-203 [MITICURE®	House dust mite induced allergic asthma (Allergen Immunotherapy)	Sublingual tablet			: e II/III mpleted*)			<ul> <li>Licensing agreement signed with ALK for providing exclusive development and distribution rights in Japan</li> <li>In-house</li> <li>Examining the future development policy</li> </ul>
House Dust Mite Sublingual Tablets]	House dust mite induced allergic rhinitis in children (Allergen Immunotherapy)	Sublingual tablet					Approval	<ul> <li>Licensing agreement signed with ALK for providing exclusive development and sales rights in Japan</li> <li>In-house</li> <li>Additional approval for the dosage and administration for pediatric use acquired in February 2018</li> </ul>

(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.

# 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.

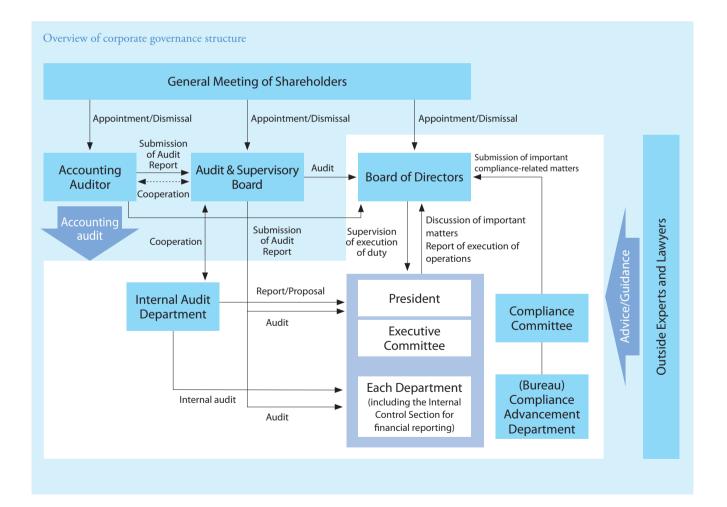
This Corporate Governance Policy is available for viewing on our website.

https://www.torii.co.jp/company/governance.html

#### 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.





Organization format Chairperson of the E of Directors Number of Directors Supervisory Board Men Selection of Indeper Officers\*

Number of Board of Directors meetings in 2017 Number of Audit & Supervisory Board meetings in 2017

at	Company with Audit & Supervisory Board	Remuneration for Each Director	Executive Director compensation consists of monthly remuneration and bonuses based on positions. The bonus
Board	Non-Executive Director		is granted based on the achievement of individual and
rs*	10 (including 2 Outside Directors)		business performance. Non-Executive Director compensation, on the other hand, consists of monthly
embers*	4 (including 2 Outside Audit & Supervisory Board Members)		remuneration based on positions. Directors (other than Outside Directors) are also subject to the Restricted Stock
endent	2 Outside Directors, 2 Outside Audit &		Compensation Plan as a medium- and long-term incentive.
	Supervisory Board Members	Remuneration for Each Audit	Monthly remuneration based on full-time/part-time
of		& Supervisory Board Member	member status
5	14 times	Accounting Auditor	Deloitte Touche Tohmatsu LLC
t	15 times	* Information as of March 28	, 2018.

# Evaluation of effectiveness of the Board of Directors

In fiscal 2017, Torii evaluated the effectiveness of the Board of Directors by questionnaire to all Directors and Audit & Supervisory Board Members. Evaluation items included schedules (the timing of the posting of annual schedules, the timing of notifications of meetings), operation (agenda items, materials, explanations, discussions), composition (number of members, member balance), and the contents of progress reports regarding Executive Director duties. Questionnaire results summarized by Independent Outside Directors showed that all items were regarded as generally reasonable and appropriate. Based on these results, we will address improvements, including further enhancement of communication between Board of Directors members in the future.

## Efforts to eliminate antisocial forces

As a good corporate citizen, Torii ensures that in order to create a better society, all employees refuse to associate with and resolutely stand against antisocial forces or groups which threaten citizens' social order or safety. Torii assigns personnel responsible for this issue to each site and provides them with training. Torii has also created manuals for handling antisocial forces and coordinated with related government agencies and a company attorney as necessary.

# Matters with possible significant impact on corporate governance

JT is Torii's parent company, and owns 54.9% 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. Torii and the parent company have reached an agreement that, as a general rule, Torii handles domestic sales of pharmaceutical products newly developed by 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 88 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 Company Auditors



Representative Director, President and ChiefExecutive Officer

#### Shoichiro Takagi

April 1983 Joined Japan Tobacco and Salt Public Corporation (currently Japan Tobacco November 2002 Senior Manager, Food Business Division, Food Business Headquarters of Japan Tobacco Inc. November 2002 Representative Diffcer of lipingshang Foods Corporation March 2007 Representative Diffcer of saint-Germain Co., Ltd Liu/2 2008 July 2008 Senior Manager, Food Business Headquarters. of Japan Tobacco Inc. July 2010 Senior Manager, Food Business Office of Japan Tobacco Inc. June 2011 Senior Manager, of Business Planning Dept., Pharmaceutical Division of Japan Tobacco Inc. June 2011 Standing Corporate Advisor of the Company June 2011 June 2011 Member of the Board, Director, Deputy Head of Pharmaceutical Marketing & Promotion Group and Vice President, Marketing Planning Dept. of the Company June 2013 Representative Director, President and Chief Executive Officer of the Company (current position)



Member of the Board, Director Head of R&D Group and Vice President, Business Development Dept.

## Atsuyuki Kakee

April 1989 Joined Japan Tobacco Inc. October 2006 Vice President, Clinical Research Planning Dept., Pharmaceutical Division. of Japan Tobacco Inc. April 2012 Vice President, Clinical Research Dept, Pharmaceutical Division of Japan Tobacco Inc. January 2015 Senior Manager of Business Planning Dept., Pharmaceutical Division. of Japan Tobacco Inc. January 2015 Deputy Head of R&D Group of the Company March 2015 Executive Vice President, Head of R&D Group of the Company April 2015 Executive Vice President, Head of R&D Group and Vice President, Business Development Dept. of the Company January 2016 Executive Vice President, Head of R&D Group and Vice President, Business Development Dept. and Medical Affairs Dept. of the Company March 2016 Member of the Board, Director, Head of R&D Group and Vice President, Business Development Dept. and Medical Affairs Dept. of the Company January 2018 Member of the Board, Director, Head of R&D Group and Vice President, Business Development Dept. of the Company (current position)



Member of the Board, Executive Director In charge of Pharmaceutical Marketing & Promotion Group

# Akihiko Tamura

April 1981 Joined the Company Joined the Company April 2002 Vice President, Head of Yokohama Branch Office of the Company November 2004 Vice President, Product Management Dept. of the Company April 2006 Vice President, Marketing Planning Dept. of the Company of the company June 2007 Executive Vice President, Marketing Planning Dept. of the Company Manning or a second June 2009 Member of the Board, Director, Head of Pharmaceutical Marketing & Promotion Group and Vice President, Marketing Planning Dept. of the Company June 2011 Member of the Board, Executive Director, Head of Pharmaceutical Marketing & Promotion Group of the Company June 2013 Member of the Board, Executive Director, Head of Pharmaceutical Marketing & Promotion Group and Vice President, Marketing Planning Dept. of the Company June 2014

June 2014 Member of the Board, Executive Director, Head of Pharmaceutical Marketing & Promotion Group of the Company

March 2017 Member of the Board, Executive Director, Pharmaceutical Marketing & Promotion Group (current position)

Member of the Board, Director

Head of Pharmaceutical Marketing & Promotion Group

Katsunobu Fujiwara

Vice President, Head of Yokohama Branch Office of the Company

June 2009 Vice President, of Product Management Dept. of the Company

June 2012 Executive Vice President, Head of Osaka Branch Office of the Company

April 2011 Senior Vice President, Product Management Dept. of the Company

June 2014 Executive Vice President, Marketing

Planning Dept. of the Company March 2017 Member of the Board, Director, Head of Pharmaceutical Marketing & Promotion Group and Vice President, Product Management Dept. of the Company

January 2018 Member of the Board, Director, Head of Pharmaceutical Marketing & Promotion Group of the Company (current position)

Planning Dept. of the Company

April 1987 Joined the Company

June 2008



Member of the Board, Executive Director Head of Planning & Administration Group

# Takahiro Umeda

April 1984 April 1984 Joined Japan Tobacco and Salt Public Corporation (currently Japan Tobacco Inc.)

June 2004 Vise President, Business Planning Dept., Division of Japan Tobacco Inc.

October 2008 Senior Manager of Business Planning Dept., Pharmaceutical Division of Japan Tobacco Inc.

November 2008 Vice President, of Corporate Planning Dept. of the Company

June 2009 Member of the Board, Director, Head of Planning & Administration Group and Vice President, Corporate Planning Dept. of the Company

June 2013 Member of the Board, Executive Director, Head of Planning & Administration Group and Vice President, Corporate Planning Dept. of the Company

March 2016 Member of the Board, Executive Director, Head of Planning & Administration Group (current position)



Head of Pharmacovigilance & Quality Assurance Group

# Yuko Kariya

April 1983 Joined the Company Joined the Company April 2007 Vice President, Customer Support Dept. of the Company June 2012 Executive Vice President, Head of Pharmacovigilance & Quality Assurance Group of the Company June 2013 Member of the Board, Director, Head of Pharmacovigilance & Quality Assurance Group of the Company (current position)



Member of the Board, Director Head of Production Group

## Masaki Sunami

April 1982 April 1982 Joined Japan Ciba-Geigy Ltd. (currently Novartis Pharma K.K.) Novertis Pharma K.K.J November 1984 Joined Nitto Electric Industrial Co., Ltd. (currently Nitto Denko Corporation) March 1991 Joined Japan Tobacco Inc. April 2011 Senior Director, Product Development Laboratories, Central Pharmaceutical Research Institute of Japan Tobacco Inc.

Research institute or Japan lobacco inc. April 2014 Deputy Head of Production Group of the Company March 2015 Member of the Board, Director, Head of Production Group of the Company (current position)



Deputy Head of Pharmaceutical Marketing & Promo Group and Vice President, Marketing Planning Dept.

# Goichi Matsuda

- April 1990 Joined Japan Tobacco Inc. January 2009 Vice President, Planning Dept., Soft Drink Business Division, Food Business Headquarters of Japan Tobacco Inc. June 2009 Member of the Board Director of JT Beverage Inc. July 2010 Vice President, Planning Dept., Soft Drink Business Division of Japan Tobacco Inc. July 2012 Senior Manager, Soft Drink Business Division of Japan Tobacco Inc. July 2012 Member of the Board, Senior Vice President of Japan Beverage Holdings Inc June 2013 Senior Vice President, Head of Beverage Business, of Japan Tobacco Inc. June 2013 Member of the Board, Director of JT Beverage Inc. January 2016 Senior Vice President, Deputy President, Pharmaceutical Business of Japan Tobacco Inc.
- January 2017 Corporate Advisor of Pharmaceutical Division of Japan Tobacco Inc

Division of Japan Tobacco Inc. March 2017 Member of the Board, Director, Deputy Head of Pharmaceutical Marketing & Promotion Group and Vice President, Marketing Planning Dept. of the Company (current position)



(Outside)

#### Masao Torikai

April 1994 Registered as lawyer (Dai-Ichi Tokyo Bar Association) April 1994 Joined Momo-o, Matsuo & Namba Joined Monto-o, Matsuo & Namba September 2000 Registered as lawyer in New York State January 2002 Partner of Momo-o, Matsuo & Namba (current position) June 2010 Audit & Supervisory Board Member of the Company June 2013 Member of the Board, Director of the Company (current position) June 2016 Outside Director serving as Audit & Supervisory Committee Member of TSUKUI CORPORATION (current position)



Member of the Board, Director (Outside)

# **Toshio Fukuoka**

April 1979 Joined Tokyo Regional Taxation Bureau July 2015 Retired from the position of District Director of Kawasaki-Kita Tax Office August 2015 Registered as tax accountant, established Toshio Fukuoka Tax Accountant Office Representative (current position) March 2016 Audit & Supervisory Board Member of the Company June 2016 Outside Audit & Supervisory Board Member of FUJI FURUKAWA ENGINEERING & CONSTRUCTION CO. LTD. (current position) March 2018 Member of the Board, Director of the Company (current position



Standing Audit & Supervisory Board Member

## Yukitomo Furuya

August 1978 Joined Yamamoto Kisen Co., Ltd. April 1979 Joined Kanto Physicians and Pharmaceuticals Sanin Marketing Co., Ltd. June 1991 Joined the Company April 2005 Vice President, Head of South Kyushu Branch office of the Company June 2007 Vice President, Head of Sendai Branch Office of the Company June 2010 Executive Vice President, Head of Nagoya Branch office of the Company June 2013 Executive Vice President, Head of South Kanto Branch Office of the Company June 2013 Executive Vice President, Head of South Kanto Branch Office of the Company March 2015 Audit & Supervisory Board Member of the Company (current position)



Standing Audit & Supervisory Board Member

# Yasuyuki Yatsumoto

April 1987 Joined Japan Tobacco Inc. April 2008 Senior General Manager, Corporate Planning Dept. of the Company July 2012 Vise President, Business Planning Dept., Pharmaceutical Division of Japan Tobacco Inc. January 2016 Senior Manager, Business Administrative Dept., Pharmaceutical Division of Japan Tobacco Inc. March 2016 Audit & Supervisory Board Member of the Company (current position)



Audit & Supervisory Board Member (Outside)

# Eiichi Izumo

April 1995 Joined Tohmatsu & Co. (currently Deloitte Touche Tohmatsu LLC) April 1998 Registered as certified public accountant July 2010 Partner of Deloitte Touche Tohmatsu LLC February 2015 Established Izumo CPA Office Representative (current position) June 2015 Outside Audit & Supervisory Board member of Benesse Holdings, Inc. (current position) March 2016 Audit & Supervisory Board Member of the Company (current position) June 2016 Outside Director serving as Audit & Supervisory Committee Member of INTAGE HOLDINGS Inc. (current position)

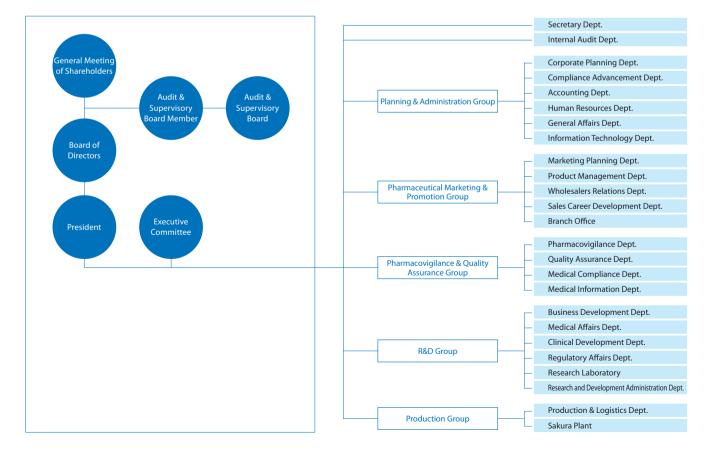


Audit & Supervisory Board Member (Outside)

#### Takaharu Matsumura

October 2000 Registered as lawyer (Tokyo Bar Association) June 2002 Joined New Tokyo International (later Bingham Sakai Mimura Aizawa - Foreign Law Joint Enterprise through office consolidation) Partner of Bingham Sakai Mimura Aizawa -Foreign Law Joint Enterprise April 2015 Partner of Anderson Mori & Tomotsune through office consolidation (current position) June 2015 Outside Director of JP-HOLDINGS, INC. (current position) April 2017 Outside Audit & Supervisory Board Member of PROPOLIFE GROUP INC. (current position) March 2018 Audit & Supervisory Board Member of the Company (current position)

# Organization



# 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

Initiatives

# **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.





# **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

# **Recall manual**

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.

# 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.

# 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 such as side effects from medical professionals.

The feedback of our information collected and 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 create and operate product information sites for medical professionals to provide a wide range of information regarding 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 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 regarding pharmaceutical products to medical professionals, collect and analyze information such as safety of products after their launch, and provide information on proper use obtained as a result of these efforts to medical professionals so 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.

# MR education and training

We have worked on human resource development of our MRs so that they can better earn the trust of medical professionals.

We carry out various education and training programs to ensure that MRs possess a high ethical standard and provide medical professionals with appropriate information. 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 MR.

# **Customer Support Dept. initiatives**

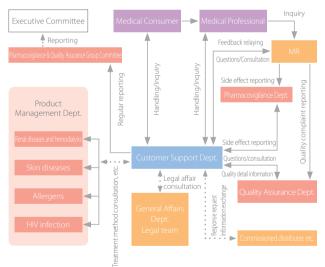
Our Customer Support Dept. directly interfaces with medical professionals, patients, and their families, handling a broad range of inquiries. The majority of the inquiries include basic drug information. No matter how excellent a pharmaceutical product may be, it is only effective when used properly. We have strived to provide highquality, appropriate, evidence-based drug information to ensure that pharmaceutical products are used properly.

# Sharing customer feedback within the Company

As an open corporate contact point with customers, the Customer Support Dept. promptly and attentively conveys accurate information regarding the proper use of pharmaceutical products. Questions and opinions from customers are collected in our database and analyzed based on their contents. The results of these analyses are shared with corresponding divisions, enabling them to consider future actions.

Going forward, we will continue to reflect customer feedback in product improvements and the provision of higher quality information, contributing to the health of patients.

Diagram on quality assurance and safety control system



#### **Customer support education**

We use telephone communication training and training based on telephone service quality diagnosis results with the aim of conscientiously dealing with each and every customer. Every month, staff members that deal with customers receive the same continuing training that MRs do, as well as actively participate in study sessions held by related divisions, workshops, and academic society meetings to learn the latest drug information, enabling them to provide customers with accurate, appropriate information.

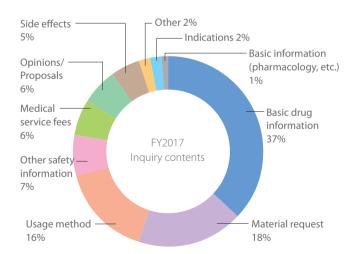
# Communication and awareness-raising through the website "Health Information" section and pamphlets for patients

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. Visitors can also read PDF or eBook versions of pamphlets such as "Self-Management of Hyperuricemia/Gout" and "Worry No Longer about Atopic Dermatitis."

We strive to contribute to the health of patients by providing information such as this.







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

# Information Disclosure

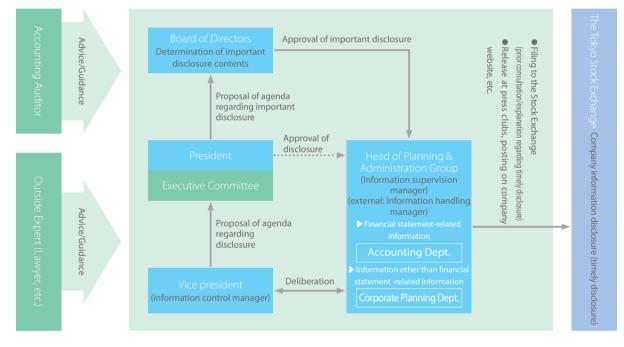
CSR Initiatives

# 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 126th General Meeting of Shareholders, held on March 28, 2018, 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 27, 2017 Resolution by Board of Directors meeting	673	24
March 28, 2018 Resolution by General Meeting of Shareholders	673	24

# 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

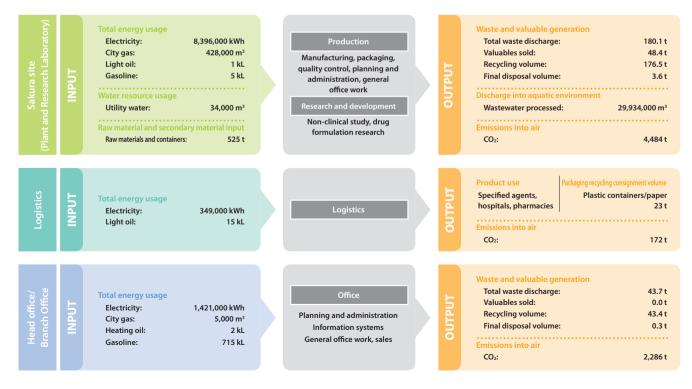
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CSR

Initiatives

	0111					😉 Achieved 😒 Unachieved
		Environmental Action Plan (FY2016 to FY2018)	FY2017 Environmental Action Plan	FY2017 Results	Evalua- tion	FY2018 Environmental Action Plan
su	Company- wide	Medium-term target: Reduce total CO <sub>2</sub> emissions in FY2018 by 3% in comparison to those of FY2015 (6,643t-CO <sub>2</sub> ) as a base FY2018 target: 6,445t-CO <sub>2</sub> or less	FY2017 target: 6,514t-CO2 or less	FY2017 results: 6,475t-CO <sub>2</sub> Vs. FY2017 target: 0.6% reduction	<b>③</b>	FY2018 target: 6,445t-CO2 or less
Greenhouse gas emissions reductions	Sakura site	FY2018 target: 4,432t-CO <sub>2</sub> or less	FY2017 target: 4,474t-CO <sub>2</sub> or less [Main measures] - Switch to LED lighting in No. 3 Plant Bldg. - Replace air conditioners with multi-split air conditioners - Replace No. 5 Plant chillers	FY2017 results: 4,484r-CO <sub>2</sub> Vs. FY2017 target: 0.2% increase (Main measures) - Sakar Werkhouse dehumidification measures (additional measure) - Main Werkhouse dehumidification measures (Main Werkhouse dehumidification measures) - Main Werkhouse del lights (additional measure) - Repair No. 5 Pandt Bidg., additional measure) - Main Main Main Main Main Main Main Main	3	FY2018 target: 4,432t-CO2 or less [Main measures] - Install warehouse building air conditioner inverter - Replace air conditioners with multi-split air - onditioner on lights with LED lights - Replace rack warehouse lighting in Sakura Warehouse with LED lights - Turn off air conditioners in Research Laboratory at night and no holidays
enhouse gas	Head office	Maintain maximum head office building CO <sup>2</sup> emissions of 370t-CO <sup>2</sup> or less FY2016 to FY2018 target: 370t-CO <sub>2</sub> or less	FY2017 target: 370t-CO <sub>2</sub> or less [Main measures] • Continue installing energy-saving vending machines • Raise awareness through head office environmental action month (ongoing) • Continue Cool Biz and Warm Biz energy-saving initiatives	FY2017 results: 334t-CO <sub>2</sub> Vs. FV2017 target: 9.7% reduction (Main measure) • Continue installing energy-saving vending machines • Raise avareness through head office environmental action month (ongoing) • Continue implementing Cool Biz and Warm Biz energy-saving initiatives	<b>(</b> :)	FY2018 target: 370t-CO2 or less [Main measures] - Continue installing energy-saving vending machines - Raise awareness through head office environmental action month (ongoing) - Continue implementing Cool Biz and Warm Biz energy-saving initiatives
Gre	Sales vehicles	FY2018 target: 1,643t-CO₂ or less	FY2017 target: 1,670t-CO: or less [Main measures] - Switch from privately-owned vehicles to company vehicles by eliminating privately owned vehicle system - Continue to select high tuel efficarcy vehicles such as hybrids - Continue promotion of eco-drive awareness and education activities	FY2017 results: 1,657t-CO <sub>2</sub> Vs. FY2017 target: 0.8% reduction Main measure - Switch from privately-owned vehicle stotem - Continue to select fuel-efficient vehicle such as hybrids - Continue promotion deco-drive awarenes and deutation activities	3	FY2018 target: 1,643t-CO2 or less [Main measures] • Continue to select fuel-efficient vehicles such as hybrids • Continue promotion of eco-drive awareness and education activities
Reduce water usage	Sakura site	Reduce total water usage to FY2015 level or below FY2016 to FY2018 target: 36,751m <sup>3</sup> or less	FY2017 target: 36,751m <sup>3</sup> or less [Main measures] • Proper use of water through water usage amount analysis	FY2017 results: 33,539m <sup>3</sup> Vs. FV2017 target: 8.7% reduction (Main measure) •Proper use of water through water usage amount analysis •Review/review Ro. 3 and No. 4 Plant BIG, bolier blow intervals •Reduce water usage by changing the start time of boiler operation for facility management	3	FY2018 target: 36,751m <sup>3</sup> or less [Main measures] • Proper use of water through water usage amount analysis
in/increase recycling rate	Sakura site	Maintain/increase recycling rate FY2016 to FY2018 target: 97% or above	FY2017 target: 97% or above [Main measures] • Thorough waste separation • Continue selling off valuables	FY2017 results: 98.0% [Main measures] • Thorough waste separation • Continue selling off valuables	$\odot$	FY2018 target: 97% or above [Main measures] • Thorough waste separation • Continue selling off valuables
Maintain/increase waste recycling rate	Head office	Maintain/increase recycling rate FY2016 to FY2018 target: 99% or above	FY2017 target: 99% or above [Main measures] ·Consign disposal to industrial waste processors with high recycling rates ·Continue selling off valuables	FY2017 results: 100% [Main measures] • Consign disposal to industrial waste processors with high recycling rates • Continue selling off valuables	3	FY2018 target: 99% or above (Main measures) • Continue to consign disposal to industrial waste processors with high recycling rates • Continue selling off valuables

# Overview of Business Activities and Their Environmental Impacts



# **Global Warming Prevention Initiatives**



# Major sales vehicle measures

Torii has implemented measures to reduce CO<sub>2</sub> emissions by sales vehicles used for MR activities through deploying hybrid cars and promoting ecologically friendly driving.

In fiscal 2017, we received 135 fuel-efficient hybrid cars, bringing the total accumulated number to 482 (total number of company-owned hybrid cars as of December 31, 2017).

We will continue to promote the use of fuel-efficient vehicles such as hybrid cars and strive to reduce the  $CO_2$  emissions from our sales vehicles.

## Compliance with the Act on Rationalizing Energy Use

Every quarter, Torii convenes a meeting of the Energy Saving Promotion Committee, which is composed of members such as energy management supervisors from related environmental departments. This committee focuses on the assessment, analysis, and management of energy usage, and engages in timely discussions aimed at rationalizing energy usage.

# Green purchasing and procurement measures

Torii promotes green purchasing of office supplies (including sales promotion goods) in accordance with its Green Purchasing Guidelines. We purchased green products in fiscal 2017 as well, and will continue to strive to purchase environmentally friendly products in the future.

We are also dedicated to using environmentally friendly packaging and containers that are free of quality issues.

## **Environmental education**

In fiscal 2017, Torii worked to raise environmental awareness by providing environmental training to new employees.

The Sakura site has formulated annual education plans for plant employees and provides regular education in accordance with its ISO 14001 environmental management system. Orientation education is also provided to newly hired and newly transferred employees.

# Measures for Creating a Recycling-Oriented Society

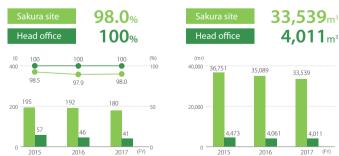
#### Main head office measures

Our head office is working to maintain and raise its waste recycling rate. We post "head office waste separation table" on each floor of the head office in order to ensure thorough sorting of waste, helping to raise recycling rates. When setting environmental action month, Torii defined reducing paper consumption as a priority issue, and has worked to reduce paper cup and photocopy paper usage. In fiscal 2017, we achieved a 100% recycling rate for the waste produced by the head office building. We will continue to maintain and improve our waste recycling rate, contributing to the creation of a recycling-oriented society.

## **Major Sakura site measures**

In fiscal 2017, as in the previous year, we continued to appropriately manage our waste disposal contractors through measures such as managing manifests and conducting inspections of final disposal sites. We also worked to improve recycling rates by promoting and expanding sales of

Waste production volume and recycling rates Water usage



valuables such as scrap iron, waste paper and other papers, and engaged in waste reduction activities.

We also continued to carry on last year's water usage reduction measures, improving the accuracy of our actual water usage volume studies and identifying futileness through detailed analysis (reviewing and revising boiler blow settings).

# 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 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.

## **Employee awareness-raising and education**

Torii defines compliance as maintaining the trust of stakeholders and not disappointing them, and distributes a compliance book that defines concrete action standards servicing as guidelines for specific actions as well as values and ethics which 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 Managers training programs, as well as hold two study sessions per year in each of our company's divisions to thoroughly ingrain compliance throughout the company.

#### **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.

# **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.



Compliance Book

Compliance Card

# Transparency Guidelines

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.



# https://www.torii.co.jp/csr/guideline.html

# Disease Awareness

# With the aim of understanding of HIV/AIDS

## As a leading company in the HIV infection field

Torii is a pharmaceutical company that carries anti-HIV products. For many years, we have provided high-quality HIV infection-related products and information on proper use in Japan. In 2017, we started marketing new Descovy Combination Tablets.

Currently, HIV/AIDS treatment has made tremendous strides, and HIV-positive patients are able to live long, healthy lives like healthy people.

However, in Japan, approximately 1,500 new HIV cases are reported every year, and there is a need for wider dissemination of HIV testing and infection preventive measures. Torii provides support for these activities, doing its utmost to satisfy its various missions as a leading company in the HIV infection field.

### With the aim of understanding of HIV/AIDS

While there have been advances in HIV/AIDS treatment, there remains a great deal of discrimination and prejudice against those with HIV/AIDS. Torii implements a red ribbon campaign in conjunction with World AIDS Day on December 1 of each year, in which red ribbons are worn to represent understanding and support for people who live with HIV/AIDS.

During this campaign, HIV/AIDS pamphlets and red ribbon lapel pins are issued to all employees, and awareness-raising activities are conducted to deepen their understanding of HIV/AIDS.

In 2017, Torii began a new initiative, sponsoring and broadcasting a segment called "messenger" on the radio station InterFM897. This segment is a project to share information on an ongoing basis to let more people be aware of HIV as a disease that can affect anyone and enable them to have an accurate knowledge of HIV, with the aim of seeking to create a world free of HIV-related discrimination and prejudice.

We consider it our responsibility to foster greater HIV/AIDS understanding and support. We will continue activities aimed at eliminating HIV/AIDS discrimination and prejudice.





The red ribbon, a symbol of HIV/AIDS understanding and support

Torii presents "messenger" – a segment broadcast on InterFM897

# "Torii-san's Allergen Immunotherapy Navigation" dedicated allergen immunotherapy site

Torii has created "Torii-san's Allergen Immunotherapy Navigation" (http://www.torii-alg.jp), a website that provides a variety of information about allergen immunotherapy (subdermal immunotherapy and sublingual immunotherapy).

This website provides easy-to-understand explanations about allergic rhinitis and allergen immunotherapy, one method of treating it. It also has a page for searching medical institutions available for consultation regarding sublingual immunotherapy.



# 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

nitiatives

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.

Four times every year, 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. 60% of distance learning program fees are subsidized for employees who have satisfied program completion requirements.

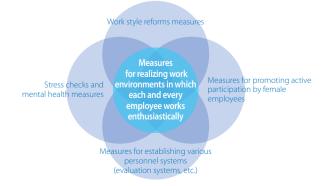
Training participation results (FY2017)

Learning and training	Number of participants
Life planning training (information provision)	24
Topic-specific training (business basics, team power, global)	41
Management training	81
Position-specific training (excluding new employee training)	267
New employee training	54
Distance learning (self-improvement)	122

# 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.



Status of measures for promoting active participation by female employees

ltem	As of December 31, 2017
% of women in the board members	7.1%
% of women in management positions	5.4%
% of women in all employees	20.3%
% of women in newly-hired employees	31.7%
Average years of service between Male vs Female	Men: 13 years and 5 months Women: 10 years
Average overtime per month	14.3 hours
Rate of taking annual paid leave	64.9%

## 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**

Every one of our work sites carries out safety and health measures in order to realize safe, 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)), and labor and management work to improve workplace environments through deliberations at Head Office Safety and Health Committee meetings held each month.

The Sakura site (Plant and Research Laboratory) also carries out Health Officer inspections (once per week), Industrial Physician inspections (once per month), Safety and Health Committee inspections (once per month), and office and work floor workplace environment measurement (once every two months) to maintain and improve workplace environments. Various problems are identified in monthly workplace meetings held by each division, and, through Safety and Health Committee meetings, labor and management deliberate regarding these problems and implement necessary measures. Furthermore, health and safety control activities are carried out from a variety of perspectives. These include not only holding traffic safety workshops and risk assessments for newly purchased devices, but also implementing annual inspections to check potential dangers in existing devices and processes, training for new General Managers when appointing Safety Officer, and participating in labor management training and other safety and health-related training.

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				
	2000	Marc		2012	
	2009	2010	2011	2012	
For the Year					
Net sales	¥37,349	¥42,416	¥45,335	¥48,717	
Gross profit	23,700	26,431	26,732	28,178	
Operating income	4,899	6,125	1,844	4,153	
Income before income taxes	6,038	6,340	1,839	5,054	
Net income	3,476	3,642	937	2,611	
Capital expenditures	1,004	1,401	797	849	
Research and development costs	1,191	1,613	5,994	4,631	
Net cash provided by (used in) operating activities	3,260	4,998	(516)	3,040	
Net cash provided by (used in) investing activities	228	(10,396)	(21,302)	3,151	
Net cash used in financing activities	(990)	(1,182)	(1,243)	(1,154)	
At Fiscal Year-End					
Total assets	¥81,433	¥85,637	¥84,885	¥87,734	
Total equity	72,034	74,641	74,246	75,832	
Number of shares issued (Thousands)	28,800	28,800	28,800	28,800	
Number of employees	878	890	905	927	
		Yen			
Per Share Data					
Total equity	¥2,545.1	¥2,637.3	¥2,623.4	¥2,679.5	
Net income	122.8	128.7	33.1	92.3	
Cash dividends	36	40	40	40	
		%			
Key Ratios					
Operating income ratio	13.1	14.4	4.1	8.5	
Return on equity (ROE)	4.9	5.0	1.3	3.5	
Return on assets (ROA)	4.3	4.3	1.1	3.0	
Shareholder's equity ratio	88.5	87.2	87.5	86.4	
Dividend payout ratio	29.3	31.1	120.8	43.4	

\*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 ¥113.00=US\$1.00, the approximate exchange rate prevailing on December 31, 2017.

\*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
March 31	March 31		December	31	December 31	December 31
2013	2014	2014*2	2015	2016	2017	2017
¥52,294	¥58,109	¥43,504	¥62,378	¥60,206	¥64,135	\$567,568
29,452	31,842	22,917	31,564	29,919	32,841	290,631
2,794	4,987	4,032	4,919	3,819	6,281	55,590
2,929	5,133	3,781	5,258	4,056	6,373	56,405
1,849	3,352	2,419	3,527	2,839	4,718	41,755
1,374	1,202	1,514	2,207	891	931	8,247
7,824	6,662	3,400	5,237	4,654	4,608	40,787
151	(201)	(609)	4,940	3,402	6,349	56,194
874	17,706	499	957	1,361	(7,593)	(67,197)
(1,181)	(1,319)	(1,410)	(1,582)	(2,289)	(1,546)	(13,685)
¥91,350	¥93,137	¥92,550	¥98,868	¥98,525	¥104,741	\$926,914
76,700	79,018	80,225	82,826	83,556	87,119	770,965
28,800	28,800	28,800	28,800	28,800	28,800	28,800
969	1,009	1,047	1,058	1,059	1,074	1,074
		Yen				U.S. dollars*1
¥2,710.2	¥2,792.1	¥2,834.8	¥2,926.8	¥2,978.8	¥3,105.7	\$27.48
65.4	118.5	85.5	124.7	100.4	168.2	1.49
40	40	40	48	48	48	0.42
		%				
5.3	8.6	9.3	7.9	6.3	9.8	
2.4	4.3	3.0	4.3	3.4	5.5	
2.1	3.6	2.6	3.7	2.9	4.6	
84.0	84.8	86.7	83.8	84.8	83.2	

61.2

33.8

46.8

38.5

47.8

28.5

# Analysis of Operating Results and Financial Condition

# Financial Results for the Year Ended December 31, 2017

The business environment for the pharmaceutical industry was very challenging in fiscal 2017 due to the promotion of healthcare system reforms aimed at regulating healthcare expenditures including measures to increase the use of generic drugs.

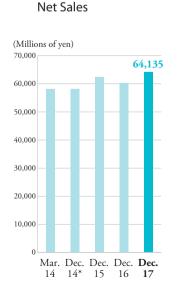
Under these circumstances, Torii strove to maximize the value of its mainstay products while focusing on prompt market penetration and expansion of new products in the following priority areas: the renal disease and hemodialysis area represented by REMITCH (an oral antipruritic agent for hemodialysis patients) and Riona Tablets (a hyperphosphatemia agent), the HIV infection area represented by Descovy Combination Tablets (an anti-HIV drug) and Genvoya Combination Tablets (an anti-HIV drug), the skin disease area represented by ANTEBATE (a topical corticosteroid), and the allergens area represented by CEDARTOLEN SUBLINGUAL DROP - Japanese Cedar Pollen (allergen immunotherapy).

# **Net Sales**

Net sales rose by ¥3,928 million (6.5%) over the previous corresponding period to ¥64,135 million, due to maximization of the value of mainstay products and the prompt market penetration and expansion of new products.

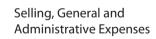
Sales of mainstay products in each priority area were as follows.

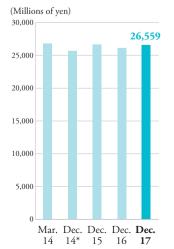
- In the renal disease and hemodialysis area, both REMITCH and Riona Tablets were affected negatively by repricing for market expansion under the drug price revisions conducted in April 2016. However, sales of Riona Tablets rose ¥611 million (10.9%) over the previous corresponding period to ¥6,245 million due to market penetration and expansion efforts, and sales of REMITCH increased by ¥192 million (1.4%) over the previous corresponding period to ¥13,838 million due to increased sales volume. In June 2017, in addition to the existing REMITCH, Torii launched orally disintegrating tablet as a new formulation.
- In the skin disease area, sales of ANTEBATE increased by ¥4 million (0.1%) to ¥6,282 million compared to the previous corresponding period.
- In the allergens area, CEDARTOLEN SUBLINGUAL DROP Japanese Cedar Pollen increased by ¥358 million (38.2%) over the previous corresponding period to ¥1,295 million due to our focusing on promoting the use of allergen immunotherapy.
- In the HIV infection area, sales of Truvada Combination Tablets (an anti-HIV drug) decreased by ¥8,813 million (69.1%) to ¥3,941 million over the previous corresponding period, but sales of its successor, Descovy Combination Tablets, which were launched in January 2017, were ¥9,218 million. Sales of Stribild Combination Tablets (an anti-HIV drug) decreased by ¥2,222 million (93.7%) to ¥148 million over the previous corresponding period, but sales of Genvoya Combination Tablets, a successor product launched in July 2016, rose by ¥4,459 million (239.0%) over the previous corresponding period to ¥6,325 million.



(Millions of yen) Dec. Dec. Change 2016 2017 ¥192 REMITCH ¥13,645 ¥13,838 1.4% 9,218 Descovy 9,218 4,459 Genvoya 1,865 6,325 239.0% 4 ANTEBATE 6,277 6,282 0.1% 611 Riona 5,634 6,245 10.9%

Sales of Mainstay Products





\*Torii has changed the closing date of the accounting period from March 31 to December 31 since FY2014. Figures from Jan to Dec 2014, the same term of the last year, is presented with Financial Results for FY2015.

# **Cost of Sales**

Cost of sales increased by ¥1,006 million (3.3%) over the previous corresponding period to ¥31,293 million due to sales volume growth and changes in sales mix among our products.

# Selling, General and Administrative Expenses

Selling, general and administrative expenses increased by ¥459 million (1.8%) over the previous corresponding period to ¥26,559 million, primarily as the result of increased selling expenses aimed at achieving prompt market penetration for new products.

#### **Operating Income, Net Income**

As a result of the above, operating income was ¥6,281 million, an increase of ¥2,462 million (64.5%) over the previous corresponding period. Net income increased by ¥1,878 million (66.1%) to ¥4,718 million compared to the previous corresponding period.

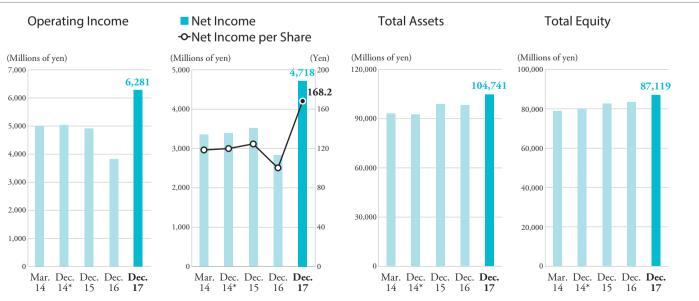
# Financial Position at December 31, 2017

#### Assets, Liabilities and Equity

Total assets increased by \$6,215 million (6.3%) from the end of the previous fiscal year to \$104,741 million as of December 31, 2017. Current assets increased by \$3,856 million (4.8%) from the end of the previous fiscal year to \$83,980 million mainly due to a \$3,453 million increase in short-term investment securities and a \$2,457 million increase in trade accounts receivable despite a \$2,789 million decrease in cash and cash equivalents. Property, plant and equipment decreased by \$2,12 million (3.7%) from the end of the previous fiscal year to \$5,540 million. Investments and other assets increased by \$2,571 million (20.3%) from the end of the previous fiscal year to \$15,220 million mainly due to a \$3,601 million increase in investment securities despite a \$737 million decrease in long-term prepaid expenses.

Total liabilities increased by \$2,653 million (17.7%) from the end of the previous fiscal year to \$17,622 million. Reasons for this increase included a \$1,963 million increase in payables and a \$629 million increase in income taxes payable.

Total equity increased by ¥3,562 million (4.3%) from the end of the previous fiscal year to ¥87,119 million. Contributing factors included surplus dividends of ¥1,346 million and net income of ¥4,718 million.



\*Torii has changed the closing date of the accounting period from March 31 to December 31 since FY2014. Figures from Jan to Dec 2014, the same term of the last year, is presented with Financial Results for FY2015.

# **Cash Flows**

At ¥35,895 million, cash and cash equivalents as of December 31, 2017 were ¥2,789 million (7.2%) lower than at the end of the previous fiscal year.

# **Cash Flows from Operating Activities**

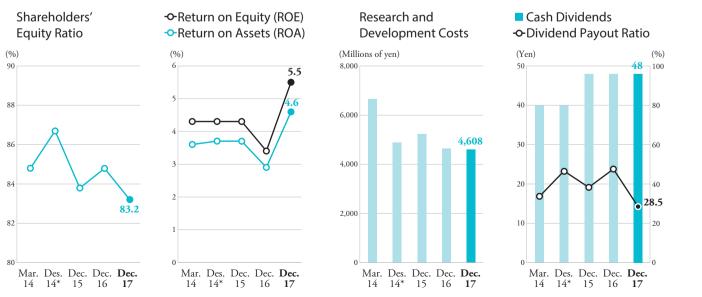
Net cash provided by operating activities amounted to ¥6,349 million (Net cash provided by operating activities for the previous corresponding year was ¥3,402 million). This result reflects income before income taxes of ¥6,373 million, depreciation and amortization of intangible assets of ¥1,174 million, a ¥1,544 million increase in trade notes and accounts payable, a ¥737 million decrease in long-term prepaid expenses, a ¥2,562 million increase in trade notes and accounts receivable and income taxes paid of ¥1,263 million.

# **Cash Flows from Investing Activities**

Net cash provided by investing activities amounted to ¥7,593 million (Net cash provided by investing activities for the previous corresponding year was ¥1,361 million). Major items included inflows of ¥2,500 million in proceeds from sale and redemption of short-term investment securities, as well as outflows of ¥5,463 million of purchases of short-term investment securities and ¥4,642 million of purchases of investment securities.

## **Cash Flows from Financial Activities**

Net cash used in financing activities amounted to ¥1,546 million consisting mainly of ¥1,346 million for dividends paid (Net cash used in financing activities for the previous corresponding period was ¥2,289 million).



\*Torii has changed the closing date of the accounting period from March 31 to December 31 since FY2014. Figures from Jan to Dec 2014, the same term of the last year, is presented with Financial Results for FY2015.

# Balance Sheet

	Millions	s of Yen	Thousands of U.S. Dollars (Note 1)
	December 31, 2017	December 31, 2016	December 31, 2017
ASSETS		2010	2017
CURRENT ASSETS:			
Cash and cash equivalents (Notes 11 and 12)	¥ 35,895	¥ 38,685	\$ 317,661
Marketable securities (Notes 3 and 11)	5,356	1,902	47,399
Receivables (Note 11):			
Trade notes	14	7	129
Trade accounts	28,972	26,514	256,394
Parent	981	192	8,684
Other	145	123	1,285
Inventories (Note 4)	10,126	10,606	89,614
Deferred tax assets (Note 8)	1,577	1,285	13,962
Prepaid expenses and other current assets	910	804	8,055
Total current assets	83,980	80,123	743,188
PROPERTY, PLANT AND EQUIPMENT:			
Land	680	680	6,023
Buildings and structures	11,504	11,441	101,805
Machinery and equipment	8,181	8,078	72,400
Furniture and fixtures	2,662	2,714	23,561
Lease assets (Note 10)	1,959	1,768	17,338
Construction in progress	97	31	861
Total	25,084	24,715	221,990
Accumulated depreciation	(19,544)	(18,962)	(172,960)
Net property, plant and equipment	5,540	5,752	49,030
INVESTMENTS AND OTHER ASSETS:			
Investment securities (Notes 3 and 11)	7,478	3,877	66,183
Software	708	788	6,266
Long-term prepaid expenses	5,748	6,486	50,869
Deferred tax assets (Note 8)	505	711	4,472
Other assets	780	785	6,904
Total investments and other assets	15,220	12,649	134,696
TOTAL	¥104,741	¥ 98,525	\$ 926,914

	Million	s of Yen	Thousands of U.S. Dollars (Note 1)
	December 31, 2017	December 31, 2016	December 31, 2017
LIABILITIES AND EQUITY			
CURRENT LIABILITIES:			
Payables (Note 11):			
Trade accounts	¥ 4,429	¥ 3,861	\$ 39,195
Parent (Note 12)	4,227	3,006	37,407
Other	3,183	3,008	28,174
Current portion of long-term lease obligations	85	199	753
Income taxes payable (Note 11)	1,396	767	12,359
Accrued expenses	746	653	6,610
Accrued employees' bonuses	684	676	6,059
Accrued bonuses to directors and Audit & Supervisory Board members	52	47	468
Other current liabilities	1,062	1,089	9,398
Total current liabilities	15,868	13,310	140,428
LONG-TERM LIABILITIES:			
Liability for retirement benefits (Note 5)	895	637	7,927

Liability for retirement benefits (Note 5)	895	637	7,927
Long-term lease obligations	465	571	4,121
Asset retirement obligations	151	150	1,337
Other long-term liabilities	241	297	2,134
Total long-term liabilities	1,753	1,658	15,520

EQUITY (Notes 6 and 7):			
Common stock—authorized, 54,000,000 shares;			
issued, 28,800,000 shares in December 2017 and 2016	5,190	5,190	45,929
Capital surplus:	6,416	6,416	56,778
Additional paid-in capital	6,416	6,416	56,778
Stock acquisition rights	9	4	87
Retained earnings:			
Legal reserve	1,297	1,297	11,482
Unappropriated	74,940	71,568	663,194
Unrealized gain on available-for-sale securities	745	558	6,594
Treasury stock—at cost, 751,603 shares in December 2017 and 751,125 shares in December 2016	(1,480)	(1,478)	(13,100)
Total equity	87,119	83,556	770,965
TOTAL	¥ 104,741	¥ 98,525	\$ 926,914

# Statement of Income

	Millions	of Yen	Thousands of U.S. Dollars (Note 1)
	Year Ended December 31, 2017	Year Ended December 31, 2016	Year Ended December 31, 2017
NET SALES	¥ 64,135	¥ 60,206	\$ 567,568
COST OF SALES (Notes 5, 10 and 12)	31,293	30,287	276,936
Gross profit	32,841	29,919	290,631
<b>SELLING, GENERAL AND ADMINISTRATIVE</b> <b>EXPENSES</b> (Notes 5, 9 and 10)	26,559	26,099	235,041
Operating income	6,281	3,819	55,590
OTHER INCOME (EXPENSES):			
Interest and dividend income	48	61	429
Gain on sales of land		86	
Loss on disposal of property, plant and equipment (Note 1)	(29)	(29)	(260)
Other—net	73	118	647
Other income (expenses) —net	92	236	815
INCOME BEFORE INCOME TAXES	6,373	4,056	56,405
INCOME TAXES (Note 8):			

Current	1,822	1,338	16,132
Deferred	(167)	(122)	(1,482)
Total income taxes	1,655	1,216	14,650
NET INCOME	¥ 4,718	¥ 2,839	\$ 41,755

	Y	U.S. Dollars	
PER SHARE OF COMMON STOCK (Note 2.r):			
Basic Net income	¥ 168.2	¥ 100.4	\$ 1.49
Diluted net income	168.2		1.49
Cash dividends applicable to the period	48.0	48.0	0.42

# Statement of Changes in Equity

		Millions of Yen							
	Outstanding Number of Shares of	Common Stock		Stock Acquisition			Unrealized Gain (Loss) on Available-for-	Treasury	
	Common Stock	(Note 6)	1	Rights(Note 6)	Reserve	Unappropriated		Stock	Total Equity
BALANCE, DECEMBER 31, 2015	28,299,232	¥ 5,190	¥ 6,416		<b>¥ 1,29</b> 7	<b>¥ 70,08</b> 7	¥ 698	¥ (863)	¥ 82,826
Net income						2,839			2,839
Cash dividends paid, ¥48.0 per share						(1,358)			(1,358)
Repurchase of treasury stock	(250,357)							(615)	(615)
Net change in the year				4			(140)		(136)
BALANCE, DECEMBER 31, 2016	28,048,875	5,190	6,416	4	1,297	71,568	558	(1,478)	83,556
Net income						4,718			4,718
Cash dividends paid, ¥48.0 per share						(1,346)			(1,346)
Repurchase of treasury stock	(478)							(1)	(1)
Net change in the year				5			186		192
BALANCE, DECEMBER 31, 2017	28,048,397	¥ 5,190	¥ 6,416	¥9	<b>¥ 1,29</b> 7	¥ 74,940	¥ 745	¥ (1,480)	¥ 87,119

	Thousands of U.S. Dollars (Note 1)							
	Common	Capital Surplus (Note 6)		Retained Ear	nings (Note 6)	Unrealized Gain (Loss) on		
	Stock (Note 6)		Stock Acquisition Rights (Note 6)	Legal Reserve	Unappropriated	Available-for- Sale Securities	Treasury Stock	Total Equity
BALANCE, DECEMBER 31, 2016	\$ 45,929	\$ 56,778	\$ 39	\$ 11,482	\$ 633,353	\$ 4,941	\$ (13,087)	\$ 739,436
Net income					41,755			41,755
Cash dividends paid, \$0.42 per share					(11,914)			(11,914)
Repurchase of treasury stock							(12)	(12)
Net change in the year			47			1,652		1,700
BALANCE, DECEMBER 31, 2017	\$ 45,929	\$ 56,778	<b>\$ 8</b> 7	\$ 11,482	\$ 663,194	\$ 6,594	\$ (13,100)	\$ 770,965

# Statement of Cash Flows

	Millions	of Yen	Thousands of U.S. Dollars (Note 1)
	Year Ended December 31, 2017	Year Ended December 31, 2016	Year Ended December 31, 2017
OPERATING ACTIVITIES:			
Income before income taxes	¥ 6,373	¥ 4,056	\$ 56,405
Adjustments for:			
Income taxes paid	(1,263)	(2,500)	(11,177)
Depreciation and amortization	1,174	1,339	10,392
Changes in assets and liabilities:			
Increase (decrease) in trade notes and accounts receivable	(2,465)	1,334	(21,815)
Decrease (increase) in inventories	480	(770)	4,251
Increase (decrease) in trade accounts payable	568	(414)	5,026
Other—net	1,481	357	13,110
Total adjustments	(23)	(653)	(211)
Net cash provided by operating activities	6,349	3,402	56,194
INVESTING ACTIVITIES:			
Purchases of marketable securities	(5,463)		(48,350)
Proceeds from sale and redemption of marketable securities	2,500	2,203	22,123
Purchases of property, plant and equipment	(529)	(500)	(4,683)
Proceeds from sale of property, plant and equipment	2	101	22
Purchases of investment securities	(4,642)	(1,611)	(41,084)
Proceeds from sale and redemption of investment securities	800	1,414	7,079
Other—net	(260)	(244)	(2,306)
Net cash provided by investing activities	(7,593)	1,361	(67,197)
FINANCING ACTIVITIES:			
Repurchase of treasury stock	(1)	(615)	(12)
Dividends paid	(1,346)	(1,358)	(11,914)
Repayments of lease obligations	(1,540)	(1,5)8)	(11,714)
Net cash used in financing activities	(198)	(2,289)	(1,738)
rect cash used in manenig activities	(1,)40)	(2,207)	(13,003)
NET DECREASE (INCREASE) IN CASH AND CASH EQUIVALENTS	(2,789)	2,475	(24,688)
CASH AND CASH EQUIVALENTS, BEGINNING OF YEAR	38,685	36,210	342,350
CASH AND CASH EQUIVALENTS, END OF YEAR	¥ 35,895	¥ 38,685	\$ 317,661

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 2016 financial statements to conform to the classifications used in 2017.

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 ¥113.00 to \$1, the approximate rate of exchange at December 31, 2017. 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 from the fiscal year ended December 31, 2016.

# **2** SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

a. Nonconsolidation—The Company has no subsidiaries as of December 31, 2017.

**b.** Cash Equivalents—Cash equivalents are short-term investments that are readily convertible into cash and exposed to insignificant risk of changes in value.

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

c. Inventories—Inventories are stated at the lower of cost, determined by the weighted-average method, or net selling value.

**d.** Marketable and Investment Securities—Marketable and investment securities are classified and accounted for, depending on management's intent as available-for-sale securities, which are reported at fair value, with unrealized gains and losses, net of applicable taxes, reported in a separate component of equity.

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

e. Property, Plant and Equipment—Property, plant and equipment are stated at cost. Depreciation of property, plant and equipment of the Company is computed by the declining-balance method while the straight-line method is applied to buildings acquired on or after April 1, 1998, and building improvements and structures acquired on or after April 1, 2016. The range of useful lives is from 15 to 50 years for buildings and structures, 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 Welfare 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.

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 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 Stock Options". 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.

**1. 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.

The Company applied ASBJ Guidance No. 26, "Guidance on Recoverability of Deferred Tax Assets," effective January 1, 2017. There was no impact from this for the year ended December 31, 2017.

**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 28,048,699 shares and 28,283,414shares for the years ended December 31, 2017 and 2016, 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, 2016.

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.

## **3** MARKETABLE AND INVESTMENT SECURITIES

Marketable and investment securities as of December 31, 2017 and 2016, consisted of the following:

	Million	Thousands of U.S. Dollars	
	December 31, 2017	December 31, 2016	December 31, 2017
Current:			
Government and corporate bonds	¥ 5,356	¥ 1,902	\$ 47,399
Total	¥ 5,356	¥ 1,902	\$ 47,399
Noncurrent:			
Equity securities	¥ 1,543	¥ 1,273	\$ 13,661
Government and corporate bonds	5,935	2,603	52,522
Total	¥ 7,478	¥ 3,877	\$ 66,183

The costs and aggregate fair values of marketable and investment securities at December 31, 2017 and 2016, were as follows:

	Millions of Yen			
December 31, 2017	Cost	Unrealized Gains	Unrealized Losses	Fair Value
Available-for-sale:				
Equity securities	¥ 357	<b>¥ 1,075</b>		¥ 1,433
Debt securities	11,297	4	¥11	11,291

December 31, 2016				
Available-for-sale:				
Equity securities	¥ 357	¥ 805		¥ 1,163
Debt securities	4,511	2	¥ 7	4,506

	Thousands of U.S. Dollars			
December 31, 2017	Cost	Unrealized Gains	Unrealized Losses	Fair Value
Available-for-sale:				
Equity securities	\$ 3,167	\$ 9,520		\$ 12,687
Debt securities	99,979	41	\$ 99	99,921

Available-for-sale securities whose fair value was not readily determinable as of December 31, 2017 and 2016, were as follows:

	Carrying Amount		
	Millions of Yen		Thousands of U.S. Dollars
	December 31, 2017	December 31, 2016	December 31, 2017
Available-for-sale—Unlisted equity securities	¥ 110	¥ 110	\$ 973
Total	¥ 110	¥ 110	\$ 973

#### 4 INVENTORIES

Inventories at December 31, 2017 and 2016, consisted of the following:

	Millions	Thousands of U.S. Dollars	
	December 31, 2017	December 31, 2016	December 31, 2017
Finished products and merchandise	¥ 6,036	¥ 6,330	\$ 53,416
Work in process	609	603	5,397
Raw materials and supplies	3,480	3,673	30,801
Total	¥ 10,126	¥ 10,606	\$ 89,614

## **5 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, 2017 and 2016, consisted of the following:

#### (1) The changes in defined benefit obligation for the years ended December 31, 2017 and 2016, were as follows:

	Millions	Thousands of U.S. Dollars	
	Year Ended December 31, 2017	Year Ended December 31, 2016	Year Ended December 31, 2017
Balance at beginning of period	¥ 8,166	¥ 8,301	\$ 72,272
Current service cost	459	446	4,064
Interest cost	<b>49</b>	49	433
Actuarial losses	74	(71)	655
Benefits paid	(511)	(559)	(4,527)
Balance at end of period	<b>¥ 8,237</b>	¥ 8,166	\$ 72,898

	Millions of Yen		
	Year Ended December 31, 2017	Year Ended December 31, 2016	Year Ended December 31, 2017
Balance at beginning of period	¥ 7,224	¥ 7,235	\$ 63,930
Expected return on plan assets	144	144	1,278
Actuarial losses	199	32	1,766
Contributions from the employer	341	338	3,020
Benefits paid	(462)	(527)	(4,092)
Balance at end of period	¥ 7,447	¥7,224	\$ 65,902

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

	Millions	Thousands of U.S. Dollars	
	December 31, 2017	December 31, 2016	December 31, 2017
Funded defined benefit obligation	<b>¥ 8,046</b>	¥ 7,980	\$ 71,205
Plan assets	(7,447)	(7,224)	(65,902)
	599	756	5,302
Unfunded defined benefit obligation	191	185	1,693
Unrecognized actuarial loss	264	(58)	2,344
Unrecognized prior service cost	(159)	(246)	(1,412)
Net liability arising from defined benefit obligation	¥ 895	¥ 637	\$ 7,927

	Millions of Yen		
	December 31, 2017	December 31, 2016	December 31, 2017
Liability for retirement benefits	¥ 895	¥ 637	\$ 7,927
Net liability arising from defined benefit obligation	¥ 895	¥ 637	\$ 7,927

#### (4) The components of net periodic benefit costs for the years ended December 31, 2017 and 2016, were as follows:

	Millions	Thousands of U.S. Dollars	
	Year Ended December 31, 2017	Year Ended December 31, 2016	Year Ended December 31, 2017
Service cost	¥ 459	¥ 446	\$ 4,064
Interest cost	<b>49</b>	49	433
Expected return on plan assets	(144)	(144)	(1,278)
Recognized actuarial losses	197	177	1,747
Amortization of prior service cost	87	87	770
Net periodic benefit costs	¥ 648	¥ 615	\$ 5,737

#### (5) Plan assets

*a. Components of plan assets* Plan assets consisted of the following:

6		
	December 31, 2017	December 31, 2016
Debt investments	43%	64%
Equity investments	29	27
General account of life insurance companies	7	7
Others	21	2
Total	100%	100%

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

#### 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, 2017 and 2016, were set forth as follows:

	Year Ended December 31, 2017	Year Ended December 31, 2016
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 ¥121 million (\$1,076 thousand) and ¥254 million are disclosed in cost of sales and selling, general and administrative expenses for the years ended December 31, 2017 and 2016 respectively, for which plan assets could not be allocated to each participating employer.

The funded status of the multiemployer pension plan at December 31, 2017 (based on information available as of March 31, 2017) and December 31, 2016 (based on information available as of March 31, 2016) to which contributions were recorded as net periodic retirement benefit costs, was as follows:

Millions of Yen		Thousands of U.S. Dollars	
	March 2017	31 2016	March 31, 2017
Fair value of plan assets	¥ 549,912	¥ 531,916	\$ 4,866,486
Sum of actuarial liabilities of pension plan and minimum actuarial reserve	547,838	538,160	4,848,128
Difference	¥ 2,074	¥ (6,243)	\$ 18,357

The Company's contribution percentage for the multiemployer pension plan at December 31, 2017 and 2016, was as follows:

	December 31, 2017	December 31, 2016
Contribution percentage	1.5%	1.5%

Notes (March 31, 2017):

1. The difference mainly resulted from prior service cost of  $\frac{1}{28,872}$  million ( $\frac{1}{255,512}$ ) thousand), surplus brought forward of  $\frac{1}{22,650}$  million ( $\frac{1}{23,454}$  thousand) and special reserve fund of  $\frac{1}{228,296}$  million ( $\frac{1}{250,415}$  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 15.5‰. The remaining term of amortization is 5 years and 0 months as of March 31, 2017.

Notes (March 31, 2016):

- 1. The difference mainly resulted from prior service cost of  $\frac{1}{34,540}$  million, deficiency brought forward of  $\frac{1}{49,751}$  million and special reserve fund of  $\frac{1}{49,751}$  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 6 years and 0 months as of March 31, 2016.

# 6 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.

# **7** STOCK OPTIONS

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

The stock options outstanding as of December 31, 2017, are as follows:

The stock option activity is as follows:

	2016 Stock Option
Vers Ended December 21, 2016	(Shares)
Year Ended December 31, 2016 Non-vested	
December 31, 2015—Outstanding	
Granted	28,000
Canceled	
Vested	
December 31, 2016—Outstanding	28,000
Vested	
December 31, 2015—Outstanding	
Vested	
Exercised	
Canceled	
December 31, 2016—Outstanding	
Year Ended December 31, 2017	
Non-vested	
December 31, 2016—Outstanding	28,000
Granted	
Canceled	(1,600)
Vested	
December 31, 2017—Outstanding	26,400
Vested	
December 31, 2016—Outstanding	
Vested	
Exercised	
Canceled	
December 31, 2017—Outstanding	
Exercise price	¥ 2,736 (\$ 24)
Average stock price at exercise	
Fair value price at grant date	¥ 427.70 (\$ 3.78)

# 8 INCOME TAXES

Total

The Company is subject to Japanese national and local income taxes, which, in the aggregate, resulted in normal effective statutory tax rates of approximately 30.9% and 33.1% for the year ended December 31, 2017 and 2016, respectively.

The tax effects of significant temporary differences, which resulted in deferred tax assets and liabilities at December 31, 2017 and 2016, are as follows:

Millions of Yen			Thousands of U.S. Dollars
	December 31, 2017	December 31, 2016	December 31, 2017
Deferred tax assets:			
Prepayment of research and development costs	¥ 1,006	¥ 878	\$ 8,911
Deferred charges for tax purposes	353	498	3,127
Liabilities for retirement benefits	274	195	2,425
Accrued bonuses to employees	211	208	1,872
Accrued enterprise taxes	100	72	885
Overdepreciation	99	116	876
Other	389	296	3,446
Less valuation allowance	(21)	(21)	(193)
Total	2,412	2,245	21,352
Deferred tax liabilities:			
Unrealized gain on available-for-sale securities	324	241	2,868
Other	5	5	49

 Net deferred tax assets
 ¥ 2,083
 ¥ 1,997
 \$ 18,434

329

247

A reconciliation between the normal effective statutory tax rate and the actual effective tax rate as reflected in the accompanying statement of income for the year ended December 31, 2017, with the corresponding figures for 2016, is as follows:

	Year Ended	Year Ended
	December 31,	December 31,
	2017	2016
Normal effective statutory tax rate	30.9%	33.1%
Expenses not deductible for income tax purposes	1.2	2.1
Dividend income deductible for income tax purposes	(0.0)	(0.0)
Per capita levy	1.1	1.7
Tax credits	(6.8)	(9.1)
Other—net	(0.4)	2.2
Actual effective tax rate	26.0%	30.0%

2,918

#### **9 RESEARCH AND DEVELOPMENT COSTS**

Research and development costs charged to income were ¥4,608 million (\$40,787 thousand) and ¥4,654 million for the year ended December 31, 2017 and 2016, respectively.

#### **10 LEASES**

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

Total rental expenses including lease payments under finance leases for the year ended December 31, 2017 and 2016, were \$1,354 million (\$11,989 thousand) and \$1,345 million, respectively.

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

	Millions of Yen	Millions of Yen Thousands of U.S. Dollars	
	2017	2017	
	Operating Leases Operating Leases		
Due within one year	¥ 83	\$ 741	
Due after one year	200	1,774	
Total	¥ 284	\$ 2,516	

#### **11** 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		
			Unrealized
December 31, 2017	Carrying Amount	Fair Value	Gain/Loss
Cash and cash equivalents	¥ 35,895	¥ 35,895	
Receivables:			
Trade accounts	28,972	28,972	
Parent	981	981	
Marketable and investment securities—Available-for-sale securities	12,724	12,724	
Total	¥ 78,574	¥ 78,574	
Payables:			
Trade accounts	¥ 4,429	¥ 4,429	
Parent	4,227	4,227	
Other	3,183	3,183	
Income taxes payable	1,396	1,396	
Total	¥ 13,236	¥ 13,236	
December 31, 2016			
Cash and cash equivalents	¥ 38,685	¥ 38,685	
Receivables:			
Trade accounts	26,514	26,514	
Parent	192	192	
Marketable and investment securities—Available-for-sale securities	5,669	5,669	
Total	¥ 71,062	¥ 71,062	
Payables:			
Trade accounts	¥ 3,861	¥ 3,861	
Parent	3,006	3,006	
Other	3,008	3,008	
Income taxes payable	767	767	
Total	¥ 10,643	¥ 10,643	

	Thousands of U.S. Dollars		
			Unrealized
December 31, 2017	Carrying Amount	Fair Value	Gain/Loss
Cash and cash equivalents	\$ 317,661	\$ 317,661	
Receivables:			
Trade accounts	256,394	256,394	
Parent	8,684	8,684	
Marketable and investment securities—Available-for-sale securities	112,609	112,609	
Total	\$ 695,350	\$ 695,350	
Payables:			
Trade accounts	\$ 39,195	\$ 39,195	
Parent	37,407	37,407	
Other	28,174	28,174	
Income taxes payable	12,359	12,359	
Total	\$ 117,137	\$ 117,137	

#### 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		
	Million	Thousands of U.S. Dollars	
	December 31, 2017	December 31, 2016	December 31, 2017
Unlisted shares	¥ 110	¥ 110	\$ 973

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

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

	Millions of Yen		
December 31, 2016	Due in 1 Year or Less	Due after 1 Year through 5 Years	Due after 5 Years through 10 Years
Cash and cash equivalents	¥ 35,895		
Receivables:			
Trade accounts	28,972		
Parent	981		
Marketable and investment securities—Available-for-sale securities with contractual maturities	5,858	<b>¥ 2,64</b> 7	<b>¥ 3,28</b> 7
Total	¥ 71,707	<b>¥ 2,64</b> 7	<b>¥ 3,28</b> 7

	Thousands of U.S. Dollars		
December 31, 2016	Due in 1 Year or Less	Due after 1 Year through 5 Years	Due after 5 Years through 10 Years
Cash and cash equivalents	\$ 317,658		
Receivables:			
Trade accounts	256,394		
Parent	8,684		
Marketable and investment securities—Available-for-sale securities with contractual maturities	51,841	\$ 23,432	\$ 29,090
Total	\$ 634,578	\$ 23,432	\$ 29,090

#### **12** RELATED PARTY TRANSACTIONS

Transactions of the Company with the parent company for the year ended December 31, 2017 and 2016, were as follows:

	Millions of Yen		Thousands of U.S. Dollars
	Year Ended December 31, 2017	Year Ended December 31, 2016	Year Ended December 31, 2017
Purchases	¥ 12,922	¥ 12,320	\$ 114,361

The balances due to or from the parent company at December 31, 2017 and 2016, were as follows:

	Millions of Yen		Thousands of U.S. Dollars
	December 31, 2017	December 31, 2016	December 31, 2017
Deposits included in cash and cash equivalents	¥ 9,836	¥ 7,091	\$ 87,045
Trade accounts payable	3,813	2,837	33,751

# **13** 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 year ended December 31, 2017 and 2016.

Sales to major customers were as follows:

	Millions of Yen		Thousands of U.S. Dollars
Name of Customer	Year Ended December 31, 2017	Year Ended December 31, 2016	Year Ended December 31, 2017
Mediceo Corporation	¥ 15,454	¥ 14,714	\$ 136,765
Alfresa Corporation	14,849	13,793	131,412
Suzuken Co., Ltd.	12,847	12,300	113,698
Toho Pharmaceutical Co., Ltd.	6,455	6,124	57,131

# Deloitte.

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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, 2017, 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, 2017, 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.

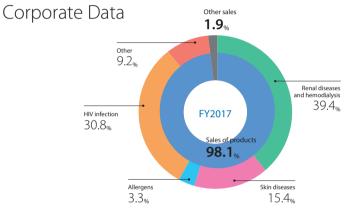
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March 19, 2018

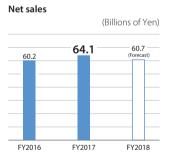
Member of Deloitte Touche Tohmatsu Limited

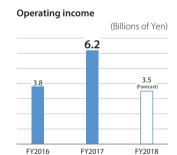
# Corporate Information



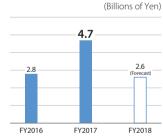


Net sales by disease area			(Millions of Yen)	
			FY2016	FY2017
Net sales		5	60,206	64,135
	Sal	les of products	59,620	62,935
		Renal diseases and hemodialysis	25,141	25,276
		Skin diseases	9,811	9,905
		Allergens	1,485	2,099
		HIV infection	17,225	19,777
		Other	5,956	5,877
	Other sales		586	1,199









# 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

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



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.

#### **Riona Tablets** Therapeutic agent for hyperphosphatemia



chronic kidney disease, including hemodialysis, peritoneal dialysis, and non-dialysis chronic kidney disease patients, by suppressing phosphate absorption into the body.

Riona is a medication which treats

hyperphosphatemia in patients with

# Descovy Combination Tablets Antiviral agent for HIV (anti-HIV drug)



Descovy is a medication which inhibits human immunodeficiency virus (HIV) reverse transcriptase

suppressing viral proliferation.

#### ANTEBATE Topical corticosteroid



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

# Genvoya Combination Tablets Antiviral agent for HIV (anti-HIV drug)



voya is a medication which inhibits human immunodeficiency virus (HIV) reverse transcriptase and integrase, suppressing viral proliferation. This anti-HIV medication works with a dosage of just one pill once daily.









URL: https://www.torii.co.jp

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