Grow sustainably as a drug discovery-based pharmaceutical company

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DATA SECTION

Editorial policy

This Integrated Report provides a wide range of information to give shareholders, investors and other stakeholders a deeper understanding of the Shionogi Group's corporate value. In addition to financial data, readers can access information about management strategy and the Group's governance, social and environmental activities.

Period under review

Fiscal 2018 (April 1, 2018–March 31, 2019)
Certain activities continuing after fiscal 2018 are also included.

Scope and organization

This Integrated Report encompasses the activities of Shionogi & Co., Ltd., 47 consolidated subsidiaries and seven affiliates. The information about our environmental activities covers all business facilities of Shionogi & Co., Ltd., and main domestic subsidiaries.

Notes concerning numerical values and graphs

All numerical values are rounded to the nearest unit, as applicable. Totals may not match due to rounding.

Forward-looking statements

This report contains forward-looking statements.
These statements are based on expectations in light of the information currently available, assumptions that are subject to risks, and uncertainties which could cause actual results to differ materially from these statements. Risks and uncertainties include general domestic and international economic conditions, such as general industry and market conditions, and changes of interest rates and currency exchange rates. These risks and uncertainties particularly apply to forward-looking statements concerning existing products and those under development. Product risks and uncertainties include, but are not limited to, completion and discontinuation of clinical trials; obtaining regulatory approvals; claims and concerns about product safety and efficacy; technological advances; adverse outcome of important litigation; domestic and foreign healthcare reforms; and changes of laws and regulations. For existing products, there are also manufacturing and marketing risks, which include, but are not limited to, inability to build manufacturing capacity to meet demand, unavailability of raw materials, and competition with other companies' products. The Company disclaims any intention or obligation to update or revise any forward-looking statements whether as a result of new information, future events, or otherwise. This report contains information on pharmaceuticals (including compounds under development), but this information is not intended to make any representations or advertisements regarding the efficacy of these pharmaceuticals no provide medical advice of any kind.

External recognition

ESG index

MSCI Japan ESG Select Leaders Index

MSCI Japan Empowering Women Index (WIN)

Member of SNAM Sustainability Index 2019

External Recognition related to IR and Sustainability

2018 Award for Excellence in Corporate Disclosure –Industries– The Securities Analysts Association of Japan

Award for Excellence in Corporate Disclosure Ranked first in the pharmaceuticals sector (Two consecutive years: FY2017, FY2018)

IR向上企業

Companies with Greatest Improvement in IR (FY2018)

2017 IR 優良企業大賞

IR Grand Prix (FY2017)

LISTED COMPANY AWARD 2017

Corporate Value Improvement Award by the Listed Company Award: Grand Prix (FY2017)

2017 Institutional Investor ALL-JAPAN EXECUTIVE TEAM MOST HONORED COMPANY

2018 All-Japan Executive Team: Ranked first in the pharmaceuticals sector (Two consecutive years: FY2017, FY2018)

2019 健康経営銘柄

Health & Productivity Stock (Four consecutive years since 2016)

2019 健康経営優良法人 Health and productivity ホワイト500

Outstanding Health & Productivity Management (Three consecutive years since 2017)

2018年認定 くるみんな

Award of Kurumin mark (Three consecutive years: 2013, 2015, 2018)

DIVERSITY MANAGEMENT SELECTION 100 2016

Selected in fiscal 2015 New Diversity Management Selection 100 project

女性活躍リーディングカンパニー 2015大阪市認証

Certified in fiscal 2015 as a leading company for women's advancement in Osaka City

Others

Aburahi Botanical Gardens receives award from Koka City for activities contributing to local community and society (FY2017)
Shionogi Techno Advance Research receives 'Eruboshi' Grade 3 award for promoting female advancement (FY2017)
Shionogi Techno Advance Research designated as Outstanding Equal Opportunities Employer by Osaka Prefecture (FY2018)
Recognized by Hiroshima Prefecture as 'I-Support Movement' organization (FY2018)
Awards from financial industry/management prizes (FY2018)
Included by Government Pension Investment Fund among selection of companies with "Most-Improved Integrated Reports" (Two consecutive years: FY2017, FY2018)
Included in selection for Excellent Integrated Reports (FY2017)

Commitment to society

WE SUPPORT UN GLOBAL COMPACT

Shionogi declares endorsement and support for UN Global Compact

Disclosure and engagement

Financial information

IR Library
http://www.shionogi.co.jp/en/ir/library/index.html

Securities report

Engagement
Conference call/General meeting of shareholders/ small meeting, etc.

Non-financial information

CSR Efforts
http://www.shionogi.co.jp/en/company/csr/index.html

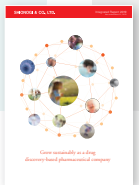
Policies
http://www.shionogi.co.jp/en/company/policy/index.html

Corporate Governance Report
http://www.shionogi.co.jp/en/static/company/cg/cg_report_en_201906.pdf

EHS Report
http://www.shionogi.co.jp/en/company/csr/activities/environment.html

Engagement
R&D meeting/Dialogue with experts/Lecture meeting/ Small meeting, etc.

Integrated Report



To our stakeholders

Shionogi traces its roots back to 1878, when it was founded as Shiono Gisaburo Shoten, a drug wholesaler. Since then, the pharmaceutical market and society have developed dramatically.

Shionogi has grown by adapting its business in line with the changing times.

However, in the last 141 years one thing has not changed – our steadfast commitment to developing and supplying even better medicines.

Even when business conditions have been tough, we have worked through the challenges without straying from our Company Policy: “Shionogi strives constantly to supply the best possible medicine to protect the health and wellbeing of the patients we serve.”

That long-held policy is firmly entrenched in our organization as Shionogi’s philosophy, supporting our growth down the years.

Going forward, we aim to grow sustainably contributing to a more vigorous society through improved healthcare and developing new medicines that give people hope.

We also want to remain the kind of company where all our employees take pride in their work and make a productive contribution every day.

Shionogi will continue to follow its unique approach, seeking out and taking on new challenges as it works to achieve its enduring goals.

M. Shiono

Motozo Shiono
Chairman of the Board and Representative Director

Isao Teshirogi, Ph.D.
President and CEO

Our philosophy

The Company Policy of Shionogi

Shionogi's purpose

Shionogi strives constantly to supply
the best possible medicine to protect the health
and wellbeing of the patients we serve.

For this purpose, Shionogi will need to

Pursue the search for even better medicines.
Produce even better medicines.
Promote awareness of these better medicines to more people so that more people will be able to use these medicines.
Research, produce, and promote in an even more economical manner.

For this purpose, Shionogi people will need to

Strive ceaselessly day after day to improve their skills.
Strive ceaselessly day after day to improve as human beings.

As a result, Shionogi people will

Find even greater satisfaction in their daily work and in their daily lives.
Find even greater improvement in the quality of their lives.
Find even greater prosperity in their lives.

Shionogi's Action Guidelines

Mission

We will deliver pharmaceuticals that offer an even higher level of satisfaction to patients, their families, and healthcare providers and improve the quality of life for patients and their families.

Vision

A company with a strong presence worldwide
A company that has pride and dreams and embraces challenges

Value

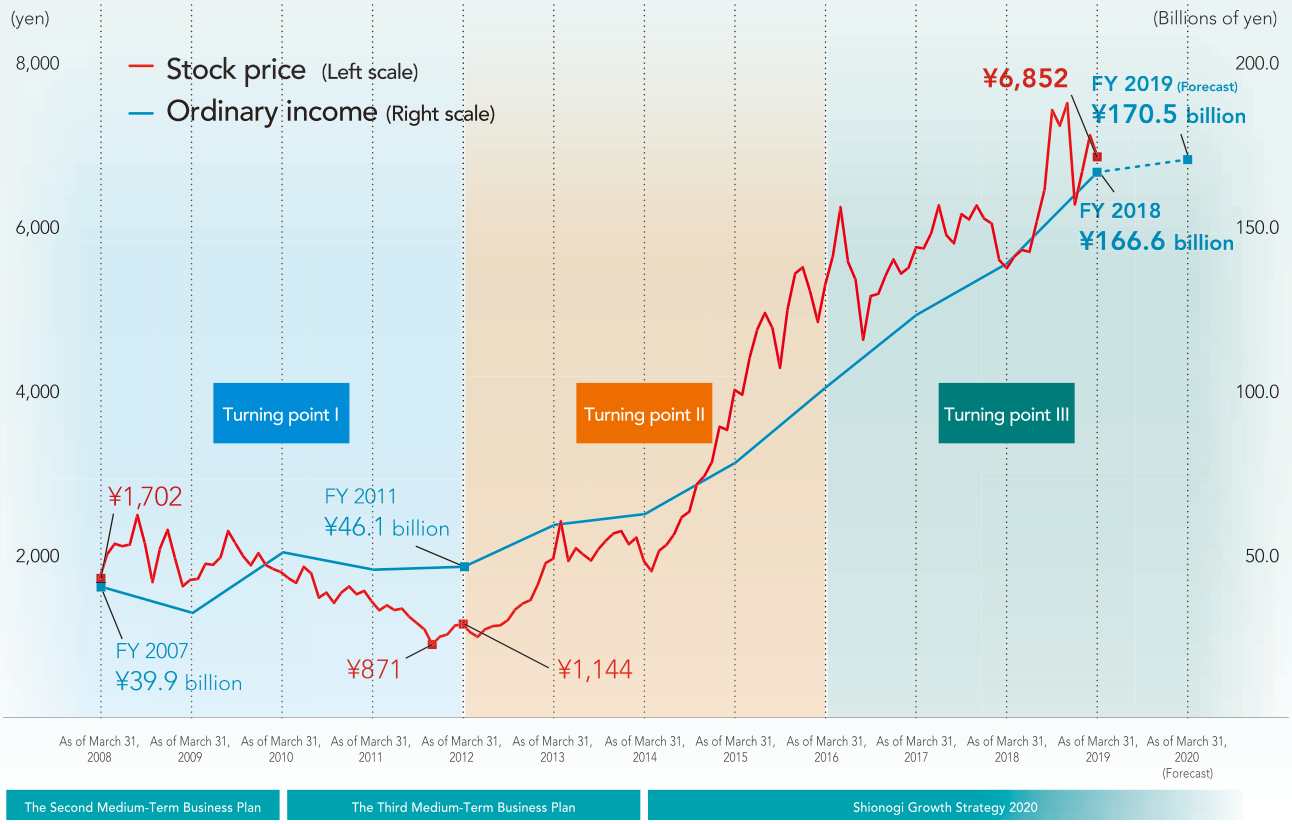
Customer focus Trust Professionalism On-site orientation
Respect for the individual

Formulated in 2004

Shionogi's efforts to create sustainable corporate value

–Three key phases of business risk unique to the pharmaceutical sector (FY2008–)–

Shionogi was founded 141 years ago in 1878 as Shiono Gisaburo Shoten, a drug wholesaler in Doshomachi, Osaka. Since then, Shionogi has grown into a major pharmaceutical manufacturer on the back of key accomplishments along the way – the proprietary development of *Shinomin*, a sulfonamide drug; the in-house discovery and launch of *Shiomarin*, the world's first oxacephem antibiotic; and the success of blockbuster drug *Crestor*, a hyperlipidemia treatment. Growth has been driven by the Japanese market, but more recently, Shionogi has made a full-scale push into the US market, starting with the acquisition of US-based drug company Sciele Pharma, Inc. However, business performance deteriorated rapidly not long after the acquisition due to the global financial crisis triggered by the collapse of Lehman Brothers and a series of failures in drug development, ending the prospects of several promising new drugs. *Crestor*, which had been driving earnings, also faced its patent expiry – one of the inevitable challenges of operating in the pharmaceutical sector. Shionogi then had to develop strategies to overcome the so-called "*Crestor* Cliff" to ensure the Group's sustained and steady growth.



Turning point I : Learning — Fiscal 2008-2011

Sciele Pharma acquisition and disruption in US business

On September 1, 2008, Shionogi acquired US-based drug company Sciele Pharma, Inc. for roughly ¥150 billion to support a full-scale push into the US market. However, barely two weeks after signing the deal, the collapse of Lehman Brothers triggered the global financial crisis. Business conditions deteriorated rapidly and Shionogi's share price slumped. In addition, two new drugs that were to be sold via Sciele Pharma dropped out in the final stages of development. All the time and cost expended on the drugs disappeared in an instant, leaving a gap of at least two years in the pipeline before the next drug candidate would be ready for approval. Meanwhile, some drugs sold by Sciele Pharma were approaching patent expiry and the company faced a string of operational issues related to product quality and supply, shaking the confidence of the company's employees.

However, Shionogi's president was unwavering in his belief that overseas markets offered the best business opportunities for the Group. The Company had taken a long time to build up its overseas sales network and there was no desire to step back now. When Shionogi launched proprietary drug *Crestor*, there was no option but to out-license it to UK-based AstraZeneca PLC due to a lack of overseas sales channels, so overseas revenue from *Crestor* was limited to royalty income. In an effort to change that situation, Shionogi decided to acquire Sciele Pharma, but the large acquisition completely changed Shionogi's financial position after being almost debt-free. Between around 2008 and 2011, Shionogi faced sustained challenges at the operational level in the wake of the Sciele Pharma acquisition, but the Company also learned a great deal during that period as it worked to put the US business on an even footing. The US business had operated at a loss until recently and is steadily moving in the right direction.

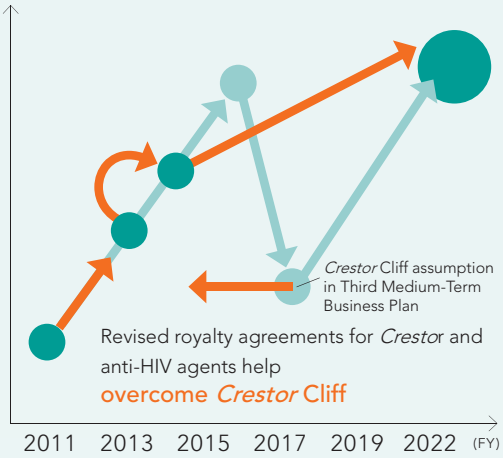
Turning point II : Confidence and Pride — Fiscal 2012-2015

Handling the *Crestor* patent expiry

Crestor became a blockbuster drug in Japan and overseas. In fiscal 2013, its peak year, *Crestor* generated royalty income of ¥65.7 billion on the back of strong sales overseas, driving Shionogi's earnings. However, patent expiry was fast-approaching. Drug developers face the so-called "patent cliff," when the end of patent protection for individual products can lead to a precipitous drop in profits. Products that generate royalty income face an even steeper patent cliff because out-licensed drugs are usually more profitable due to lower costs. Facing the loss of more than ¥60 billion in operating income in just a couple of years, Shionogi needed to do something to take the situation into its own hands, rather than awaiting a fate tied to conditions at another drug company.

In 2013, just three years before the *Crestor* patent expiry, Shionogi and UK partner AstraZeneca PLC agreed to modify the terms of the *Crestor* royalty agreement, lowering the effective royalty rate in return for extending the period of royalty payments until 2023 at the latest. While the new agreement brought forward the *Crestor* Cliff – the biggest issue for management at the time – it ensured Shionogi would continue to receive royalty income from the drug even after the patent expired, providing a source of income to support growth over the medium and long term.

Generating stable profits to support medium- and long-term growth



Anti-HIV agent *Tivicay* – a new growth driver

While efforts were being made to modify the royalty agreement for *Crestor*, Shionogi was also making steady progress with the development of a next-generation of strategic products.

One of those drugs was anti-HIV agent *Tivicay* (dolutegravir), developed in-house and out-licensed to UK-based ViiV Healthcare Ltd. *Tivicay* and combination drug *Triumeq* became blockbuster drugs, together generating global sales of £1.3 billion in 2015, the third year since launch. Despite the phased but large reduction in royalty income from *Crestor*, Shionogi's total royalty income grew to ¥114.9 billion in fiscal 2016. The revenue sharing agreement for *Tivicay* was initially based on the joint development of the drug by Shionogi and ViiV Healthcare, but the agreement was modified in 2012. Shionogi agreed to transfer the commercial rights for *Tivicay* and related products to ViiV Healthcare in exchange for a 10% stake in ViiV Healthcare. As a result, Shionogi started receiving dividend payments as a shareholder in the company, as well as royalty income for *Tivicay*. Dividends increased as ViiV Healthcare's earnings grew, with dividends received by Shionogi exceeding ¥10 billion in fiscal 2015. The changes to *Crestor* and *Tivicay* royalty agreements enabled Shionogi to comfortably overcome the *Crestor* Cliff.

Turning point III : From Complacency to Revival — Fiscal 2016-

Updates to SGS2020

The strong growth in earnings after the *Crestor* Cliff gave our employees' confidence, but there were also signs of a drop in intensity. The modified royalty agreements did not reinforce our underlying business; they had merely shifted the main source of royalty income from *Crestor* to the HIV franchise of dolutegravir-based drugs. Despite that, there was a growing sense of complacency within the Company that we had beaten the *Crestor* Cliff by increasing profits.

At the same time, changes in society and our business environment converged, prompting us to update the Medium-Term Business Plan (SGS2020) in October 2016 in order to sustain growth after 2020. Under the updated plan, we have channeled business resources into areas where Shionogi has a strong position, aiming to grow sustainably as a drug discovery-based pharmaceutical company contributing to a more vigorous society through improved healthcare and helping to solve social issues.

We are now in the final stages of the plan. Based on a shared sense of urgency, every employee is working together to achieve the plan's targets and laying the foundations for the next phase of growth from 2020, which will mean overcoming the "dolutegravir cliff" in about a decade.

Medium-Term Business Plan
SGS2020 (2014-2020)

Grow sustainably as a drug discovery-based pharmaceutical company contributing to a more vigorous society through improved healthcare

In March 2014, we launched Shionogi Growth Strategy 2020 (SGS2020), which set out our medium-term vision for Shionogi. We updated the plan in October 2016 to raise our goals even further. Under the plan's vision – Grow sustainably as a drug discovery-based pharmaceutical company contributing to a more vigorous society through improved healthcare – the Group is making a concerted effort to achieve its targets.
In this section, we summarize the goals of the plan and the key themes for a drug discovery-based pharmaceutical company, given the increasing complexity of drug development and continued growth in the generic drug market.

Basic Strategy in Updated SGS2020

Vision

Grow sustainably as a drug discovery-based pharmaceutical company contributing to a more vigorous society through improved healthcare

Growth Regions and Areas		Keys to Growth
Focusing on Japan and the US Strengthening bases in Europe and Asia	+	Addressing society's needs
Infectious diseases, pain / CNS disorders		Balancing innovation and healthcare affordability

Our vision for Shionogi based on two themes

1 A continued commitment to drug discovery

Pharmaceutical companies are focused on drug discovery. That goes without saying, but at Shionogi, our commitment to drug discovery is particularly strong.

Shionogi ranks 45th worldwide by sales in the global pharmaceutical market (fiscal 2016). Many pharmaceutical companies of similar size have diversified their businesses into generic drugs. In contrast, Shionogi's original pipeline ratio is roughly 70%, underscoring our proprietary strengths in drug discovery. Those capabilities are creating a steady stream of new global drugs, such as hyperlipidemia treatment *Crestor* and anti-HIV agent *Tivicay*.

We are also working to discover new products in-house because it aligns with our corporate policy: "Shionogi strives constantly to supply the best possible medicine to protect the health and wellbeing of the patients we serve." Given those factors, we have declared our commitment to growing as a drug discovery-based pharmaceutical company. That vision has made our path clearer. We have completely exited the generic drug market, where we had a small presence when SGS2020 was launched, and international investors have welcomed our move to clarify Shionogi's corporate character.

2 A desire to "grow sustainably contributing to a more vigorous society through improved healthcare"

In the original SGS2020 plan, announced in early 2014, our vision was to "Grow as a drug discovery-based pharmaceutical company." In the latest version, which was updated in 2016, we have expanded that vision to include the phrase "contributing to a more vigorous society through improved healthcare."

Recently, amid growing public controversy about rising health costs, pharmaceutical companies have faced severe criticism about the high price of some medicines. The public is starting to push back against the argument that high prices are warranted by the revolutionary nature of new drugs. As a drug company, we have to seriously address those concerns. Looking beyond our basic value to society as a drug manufacturer, we have to ask ourselves what kind of value we can create for society through drug discovery. That means looking at ways to solve broader social issues. That approach will also help to increase Shionogi's corporate value – another reason why we added the phrase "contributing to a more vigorous society through improved healthcare."

Targeting resources on promising growth markets and therapeutic areas

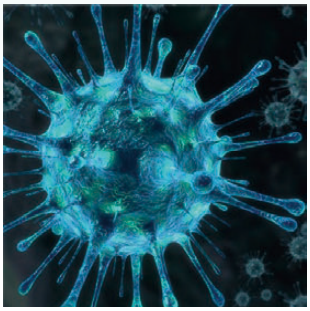
1 Focusing on Japan and the US

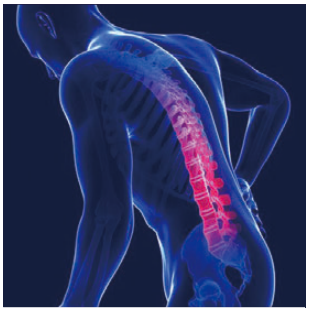
Shionogi has grown its business by focusing on the Japanese market. Under the updated SGS2020 plan, we are accelerating the Group's overseas business expansion. Our priority region is the US, the world's largest pharmaceutical market. The first objective is to put in place systems that will allow us to develop and sell products as we do in Japan. We have already made some good progress. Shionogi teams in Japan and the US jointly developed proprietary drug *Symproic*, a treatment for opioid-induced constipation (OIC), and we are developing a new antibacterial drug as part of our response to the threat of antimicrobial resistance (AMR).

Meanwhile, in Japan's super-aging society, there is a growing need for longer healthy life expectancy. Shionogi is focusing on the therapeutic area of pain / CNS disorders. We are helping to make life better for patients and their families by targeting symptoms that cause a significant reduction in quality of life (QOL), such as pain and reduced cognitive function caused by certain medical conditions.

2 Infectious diseases, pain / CNS disorders

We are focusing on infectious diseases and pain / CNS disorders as therapeutic areas where we can maximize our strengths in small-molecule drug discovery. Our strong position in infectious disease treatments is well-recognized, to the extent that the Shionogi name is synonymous with antibiotics in Japan, while small-molecule drugs are effective in the treatment of pain and CNS disorders. Those factors are behind our decision to select infectious diseases and pain / CNS disorders as priority areas. Infectious diseases are responsible for a high proportion of deaths worldwide each year and many elderly people in Japan succumb to pneumonia. We are already seeing a number of promising new treatments for infectious diseases from drug makers worldwide, while Shionogi has launched anti-HIV agents and flu drug *Xofluza* in recent years. Changes in the external environment mean pain / CNS disorders are a globally important treatment area. An increase in average life expectancy has led to a rise in the number of people living with medical conditions, resulting in greater need for medicines that alleviate pain and suffering associated with chronic disease. In this therapeutic area, we are developing drugs to treat cancer pain – a field where Shionogi already has a strong track record – as well as treatments for depression, Alzheimer's disease and chronic coughing.





Message from the President

Grow Sustainably as a Drug Discovery-Based Pharmaceutical Company Contributing to a More Vigorous Society Through Improved Healthcare

Progress with the SGS2020 Medium-Term Business Plan

In fiscal 2018 (April 1, 2018 to March 31, 2019), the fifth year of our current Medium-Term Business Plan – Shionogi Growth Strategy 2020 (SGS2020), sales increased for the fourth successive year and profits hit another record-high. We achieved the plan's fiscal 2020 targets for return on equity (ROE) and return on invested capital (ROIC) in fiscal 2016 and fiscal 2017, respectively, and they have both risen further since then. In fiscal 2018, ROE exceeded 20% for the first time, underscoring the real progress we have made across our business. In the year under review, we also achieved our fiscal 2020 target for ordinary income – one of the plan's growth KPIs. As of the end of fiscal 2018, we are making steady progress against our targets in all areas, except for new product sales and the cash conversion cycle (CCC). In fiscal 2018, the CCC increased by 2.7 months from the previous fiscal year, mainly due to a longer inventory turnover period. That reflected a substantial drop in cost of goods sold (COGS) amid a steep decline in sales of *Crestor* and *Irbetan*, which both have high COGS ratios, due to the impact of generics. Supported by greater focus on management efficiency in all parts of the Group as well as operational improvements, we are targeting an industry-leading CCC of 7.0 months in fiscal 2020 by working closely with Shionogi Pharma Co., Ltd. to rigorously control inventory.

During SGS2020, global sales of *Tivicay*, *Triumeq* and *Juluca*, which are all based on our anti-HIV agent dolutegravir, have continued to increase, driving the Group's growth. We have also significantly strengthened our ability to develop globally marketable products on the basis of our experience with *Xofluza*, *Symproic* and cefiderocol. Meanwhile, drug candidates from our pipeline are gaining steady momentum as future growth drivers, particularly our eight strategic products. With a solid lineup of new domestic and overseas drugs now in place, the domestic business is poised to move into a new phase of sales growth. However, one issue we still need to tackle is the large shortfall in sales of new products compared with fiscal 2020 targets. After achieving our target of ¥100 billion in fiscal 2019, we will turn our attention to reaching the targets in SGS2020 by stepping up efforts to reinforce our domestic and overseas businesses.

Sustained efforts have led to a significant improvement in the earnings structure, but during that process there have been many missteps and setbacks. Learning from those mistakes, we now have a clearer picture of three key points on which we need to maintain focus (see below) and the obstacles that stand in the way of the Group's medium- and long-term growth. We have no intention of letting up now as we enter the final stages of SGS2020.

Please refer to pages 6–7 for more details about SGS2020.
More information about Shionogi's performance in fiscal 2018 can be found on pages 82–83.

Net sales
¥363.7billion
(Y o Y +5.5%)
Increased for 4 consecutive years

Operating income
¥138.5billion
(Y o Y +20.2%)
Higher than the levels achieved in prior fiscal years for 4 consecutive years

Ordinary income
¥166.6billion
(Y o Y +20.1%)
Higher than the levels achieved in prior fiscal years for 7 consecutive years

Profit attributable to owners of parent
¥132.8billion
(Y o Y +21.9%)
Higher than the levels achieved in prior fiscal years for 3 consecutive years

		FY2020 target	FY2019 target	FY2018 target*1	FY2018 results	FY2017 results
Growth	Sales of new products*2	¥200.0 billion	¥100.6 billion	¥72.1 billion	¥83.1 billion	¥52.9 billion
	Ordinary Income	¥150.0 billion	¥170.5 billion	¥140.0 billion	¥166.6 billion	¥138.7 billion
Efficiency	ROIC*3	Over 13.5%	Over 15.0%	Over 14.5%	16.5%	14.9%
	CCC*4	5.5 months→ Less than 7.0 months	Less than 7.6 months	6.1 months	8.9 months	6.2 months
	Original pipeline ratio	Over 50%	Over 50%	Over 50%	69%	74%
Shareholder return	ROE	Over 15.0%	Over 18.0%	Over 17.0%	20.9%	19.4%
	DOE	Over 4.0%	Over 4.3%	4.3%	4.6%	4.6%

*1 Target set on May 9, 2018 *2 New products: New Products were defined in Updates to SGS2020 issued on October 31, 2016
*3 ROIC: Return on invested capital *4 CCC: Cash Conversion Cycle

Continuing to focus on the three key points that define Shionogi

(1) Drive innovation primarily through R&D

Supported by our world-class SAR engine for small molecule drug discovery, which allows us to efficiently create innovative small-molecule pharmaceuticals, we have successfully launched a stream of competitive, ground-breaking new drugs such as *Crestor*, *Tivicay* and *Xofluza*, despite having significantly fewer R&D personnel and lower budgets than major global pharmaceutical companies.

Those successes reflect our dogged pursuit of return on invested capital, which is helping us close in on the level of return that a next-generation drug company should be achieving. We consistently achieve a level of productivity in progressing the development of and obtaining approvals for our compounds that is substantially higher than would be expected based on our level of investment in R&D personnel and other resources. This underscores our very high level of R&D efficiency compared with other pharmaceutical companies. That overachievement explains our strong reputation in the industry at the moment. Over the next decade, we will strive to create value using new business models, but our overarching aim will be to harness innovation in the pursuit of value, backed by efficient and effective R&D capabilities from product inception through to realization.

Please refer to pages 20–29 for more details about how Shionogi drives innovation.
More information about R&D activities can be found on pages 76–79.

(2) Balance the needs of four stakeholder groups

Shionogi fully understands that companies rely heavily on four main stakeholder groups – shareholders and investors, customers, society and employees. Optimally balancing their needs is crucial to increasing corporate value. When we are unable to satisfy the demands of one of those groups, senior management has a duty to secure their understanding through dialog. We have seen many cases in recent years where companies that failed to build balanced relationships between those four stakeholder groups have suffered precipitous declines in corporate value as a result. At Shionogi, the ethos of our management approach is to ensure balanced relationships with our four stakeholder groups while responding flexibly to any changes in their interests and needs.

Please refer to pages 70–71 for more details about Shionogi's stakeholder engagement.

(3) Pursue efficiency

One of Shionogi's characteristics is its robust management structure, which allows us to intensively pursue efficiency to achieve our disclosed objectives.

By overhauling existing cost structures and approaches, we have been able to achieve an exceptionally high operating margin (38.1% in fiscal 2018) compared with peers, while also continuing to drive innovation to support growth. That firm commitment to targets and high operating margin are also key characteristics of Shionogi. We intend to continue targeting highly efficient business operations that are resilient to change.

Tackling three key issues to deliver growth over the longer term

To continue growing in the medium and long term, we have to further reinforce our business to prepare for the "dolutegravir cliff", when profits from our HIV franchise are expected to decline due to expiration of patents for dolutegravir. During SGS2020, we are stepping up efforts to tackle a number of priority issues that will help us successfully overcome the dolutegravir cliff. We have about a decade to get ready for the cliff. That might seem like a long time, but in the pharmaceutical sector, which takes many years to research and develop new drugs, the clock is already ticking. That's why we are now sending quarterly messages to all Group employees and encouraging dialog to foster a shared sense of urgency and raise awareness about the changes that need to be made.

Three key issues to deliver longer-term growth

Issue 1

Discover and develop next-generation growth drivers to take over from dolutegravir

Issue 2

Reinforce the domestic business and establish a global presence

Issue 3

Create new value and reinforce the business base

In the near term, we expect a steady stream of new products to generate a certain level of growth, supported by stable profits from our HIV franchise. Looking further ahead, we plan to accelerate global drug development and create a next-generation of growth drivers to take over from dolutegravir. In parallel, we will reinforce the domestic business – our main source of sales – and establish a global presence. However, even if we do succeed in finding new growth drivers to overcome the dolutegravir cliff, the next patent cliff awaits, which is one of the constant risks associated with doing business in the pharmaceutical field. To mitigate the impact, we have to tackle another issue – create and provide new value across all areas of healthcare, not just pharmaceuticals, to build a stable earnings structure.

Issue 1 Discover and develop next-generation growth drivers to take over from dolutegravir

I have already highlighted Shionogi's powerful R&D capabilities, which are anchored by a strong commitment to innovation. We have made particularly good progress in recent years thanks to improvements to our drug development infrastructure overseas and a growing track record built up through the global development of proprietary drugs such as *Xofluza*, one of our new family of small-molecule drugs. However, there are still many areas we need to improve on, such as carefully selecting and accelerating the development of new drug candidates based on criteria such as marketability and competitiveness versus rival products. For a company of our size to take on the global majors, we need to hone our capabilities in three key areas: drug discovery, development momentum, and business judgment. In drug discovery, we will channel management resources into treatment categories or technologies where we already have a strong position in order to build a pipeline of competitive drug candidates that meet the needs in the society and the healthcare area. Regarding development momentum, we need to rapidly build a body of clinical evidence in strategic development projects to maintain and improve our competitiveness. And in business judgment, we have to be able to make the right decisions about drug candidates from various different perspectives. All three areas must work efficiently together if we want to create promising drug candidates and launch commercially competitive products by 2028. Poor R&D productivity is under the spotlight in the pharmaceutical sector. Against that backdrop, we aim to increase our drug development success rate by using the best drug discovery approach for each target therapeutic area. That means trying different drug modalities*1, particularly peptides, nucleic acids and other so-called middle-sized molecules, as well as small-molecule drugs, one of Shionogi's strengths. We will also continually explore potential business alliances to actively create and cultivate new growth drivers.

*1 Modality is a term used to classify different groups of therapeutic agents based on their physical properties. Modalities include small or middle-sized molecule drugs, protein drugs such as antibody drugs, cell therapies, and regenerative therapies.

Please refer to pages 20–29 for more details about how Shionogi drives innovation, and pages 76–79 for a more in-depth look at the Group's R&D.

Issue 2 Reinforce the domestic business and establish a global presence

To drive Shionogi's medium- and long-term growth, we will continue to focus on our home market of Japan and the US, the world's largest pharmaceutical market, but we also aim to build up our business in China, which is projected to see the strongest growth in pharmaceutical demand over the next decade. We still need to reinforce our business base in some countries in Europe and the ASEAN region, which is establishing new drug approval systems. However, ensuring we have strong positions in Japan and in the US and tapping into China's growth will be crucial to expanding our sales channels in other regions. We plan to build a solid business base worldwide by reinforcing proprietary sales capabilities and carefully identifying regions and therapeutic areas where partnerships are the best approach.

In Japan, the activities of Shionogi medical representatives (MRs) have been underpinned by the concept of "detail & trace" for more than 60 years – which involves carefully explaining drug safety characteristics, as well as efficacy, and checking whether our products are achieving the intended

outcomes for patients. We are backing up that existing approach with IT investment that gives us a clearer picture of MR behavior and upgrading infrastructure so that we can constantly update and share information with MRs about the medical institutions they should visit and the data they should communicate. We are starting to see some solid results from that approach, albeit at a gradual pace.

In the US, we plan to rebuild our sales structure centered on *Mulpleta*, our drug for the treatment of thrombocytopenia in adult patients with chronic liver disease who are scheduled to undergo a procedure, which was launched in fiscal 2018, and cefiderocol, which is currently under review with the U.S. Food and Drug Administration (FDA). We plan to increase marketing efficiency by focusing on hospital/highly specialized businesses, a category into which both drugs fit. That approach, together with profits from sales partners that distribute our vaginal atrophy treatment *Osphena* and opioid-induced constipation (OIC) treatment *Symproic*, should support a highly efficient business in the US. As one of our outside directors pointed out, if Shionogi fails to build a proprietary sales capability in the US in the next few years, it should consider becoming just an R&D-focused business in the US market. To ensure that does not happen, we will step up efforts to establish our presence in the US, including the launch of new products and the advancement of drug candidates in late-stage development.

Please refer to page 80 for more details about the domestic business.
Please refer to page 81 for more details about our overseas business.

Issue 3

Create new value and reinforce the business base

The current approach to social security provision is under question amid increasingly stretched healthcare budgets in advanced markets. Meanwhile, AI and ICT have opened the door to new ways of doing business in the pharmaceutical sector that were not possible in the past. Those trends mean we can no longer rely on our existing business model based solely on selling pharmaceutical products. Companies from many other sectors have already moved into the healthcare field and current social welfare systems are set to undergo major changes. As patients gain access to more information and select their own preferred type of healthcare service, a drug could just become one of many options in the healthcare field.

To continue growing over the next 10 to 20 years in that environment, we will need to use our strengths in the creation of innovative drugs to make a sustained contribution to patient treatment and QOL. We will also need to continually search for healthcare areas where our expertise, skills, and experience in R&D can be put to good use in other services. We want to be a company that continues to help extend healthy life expectancy by exploring the possibilities of therapeutic and preventative vaccines, digital treatment option such as healthcare apps, and information services, and by drilling down into the issues that people face in all areas of healthcare, from pre-symptomatic and preventive care through diagnosis and treatment.

Targeting sustained growth after 2020

Drastic and diverse changes in the pharmaceutical sector environment and peoples' lifestyles and values are forcing us to rethink the role that Shionogi should play in the future. Of course, as the President of Shionogi, I have absolutely no intention of letting up on efforts to achieve our targets for fiscal year 2020, the final year of SGS2020, which underscores our clear commitment to stakeholders. However, at the same time, we are investing a significant amount of time talking to stakeholders about the kind of company we want Shionogi to be after 2020, without being limited by existing approaches, and the growth strategies we will need to make that happen.

We have identified three major trends in our environment that are likely to have major impact on our business in the future:

(1) Growth in the global population and increasingly aging societies in upper middle-income countries
(2) A faster pace of, and greater impact from, climate change and other environmental trends compared with the previous decade, leading to changes in the prevalence of certain diseases and healthcare needs.
(3) Revolutionary advances in IT and AI

We are approaching a major turning point in the management strategies we must utilize to effectively navigate our business environment, responding to those major trends, and the initiatives we develop in response have the potential to fundamentally affect the future of the Company. It will be extremely difficult for any single drug company to respond to the changes by itself. Shionogi has to forge alliances both with other pharmaceutical companies and with partners in other industries to complement its strengths and create new platforms in the healthcare field. If we do not, Shionogi will struggle to adapt and stay competitive. To form alliances, potential partners have to be able to easily identify and have confidence in Shionogi's strengths. To ensure Shionogi keeps growing after 2020, we therefore need to reinforce and maximize our strengths and work with partners to create new business platforms.

Cultivating people to support Shionogi's sustained growth

While partnerships with other companies will be crucial, there is nothing more important than our own people, who are the basis of Shionogi's strengths. Encouraging friendly competition between employees while respecting different values helps to drive various types of innovation. To grow as a company, we have to build an organization that blends knowledge and expertise from various sources by bringing together different people. That means recruiting younger employees who are not wedded to conventional wisdom and fixed ideas, and respecting diversity, including people with global values. Based on that thinking, we formulated a Diversity Vision in fiscal 2018 to ensure that all of our employees are aware of our diversity & inclusion (D&I) initiatives. Through internal and external activities, we are helping employees deepen their understanding of D&I, while also raising awareness about different work practices and other workplace trends. Active efforts by management to promote D&I will be meaningless unless employees are also on board. That's why it will be very important to ensure D&I is incorporated into every aspect of our operations over the next few years.

Shionogi has also introduced personnel training programs tailored to a wide range of people, from young employees and mid-career personnel to senior managers. The programs are attended by people from different teams across our organization to stimulate communication and encourage friendly competition. Our goal is to promote diversity and cultivate the next generation of business leaders.

The President's Management Seminar, which I have held for seven years, starting in 2012, is another way we are working to train future leaders. My seminar, and the Management Seminars run by division heads, are used to foster the next-generation of business leaders and senior managers from the current manager cohort. To ensure that our senior managers have a full and detailed understanding of the Group's operations, executive officers have to work as general managers at a minimum of two divisions, including a division where they have no previous experience, while candidates for senior managerial positions are required to have management experience as the president of a Group company and as a non-executive director or auditor at a Group company. These various initiatives are designed to promote and sustain diversity.

Another important part of a manager's job at Shionogi is to identify their successor. At the minimum, the next person to fill a role has to meet two criteria. First, as the manager of a pharmaceutical company, they must have specialist knowledge about pharmaceuticals and a detailed understanding of the pharmaceutical business, as well as a deep attachment to our industry. For a company seeking to form an alliance with Shionogi, it would be inconceivable for them to deal with the president of a pharmaceutical company who has no interest or knowledge in our industry. Second, managerial candidates need to have a vision for Shionogi 10 or 20 years in the future. New drugs take a very long time to develop, so we need to flexibly adapt our research and development strategies in line with projected changes in society, which is in constant flux. Today's business leaders have to be better at envisioning future conditions and incorporating that outlook into business management. That means they need to understand trends in IT and social welfare systems and have detailed knowledge about topics such as advanced economies, emerging economies and climate change. That's the type of person we want to lead Shionogi in the future.

Please refer to pages 50–53 for more details about personnel development and diversity.

ESG initiatives

The Sustainable Development Goals (SDGs) adopted by the United Nations in 2015 and other trends are spurring growing interest in environment, social and governance (ESG) issues worldwide, which is putting more pressure on companies to play a greater role in realizing sustainable societies. As mentioned earlier, we face climate change, a rising global population and aging societies in upper middle income countries. Shionogi needs to address those accelerating environmental and social changes in order to grow sustainably by contributing to a more vigorous society through improved healthcare. We have identified the material issues that matter most to Shionogi (materiality) and disclosed them to stakeholders. The social issues that we strive to address, and driving innovation to help solve those issues, define our priorities, and we have accordingly highlighted a number of key ESG issues that Shionogi needs to tackle as a public entity. As with our efforts in personnel development, senior managers have to do their part to further strengthen our corporate culture, characterized by the phrase, "automatically thinking and doing the right thing at all times."

Please refer to pages 16–17 for more details about the Shionogi Group material issues.

Governance and compliance

Reinforcing governance and ensuring compliance are vital to sustaining our business activities in the long term. Shionogi has already taken numerous steps to improve corporate governance. We have put in place systems and set out rules to ensure rapid, bold decision-making processes that are transparent and fair from the perspective of all our stakeholders – from patients and medical professionals to shareholders and investors, communities and employees. Aiming to achieve the highest levels of governance, Shionogi was also one of the first companies in Japan to appoint outside directors in 2009, the year after I became President, and we have worked to create a more diverse board of directors, including the appointment of the first female director from within the company in 2015. With compliance, we strive to ensure our staff comply with social norms and behave in an ethical manner as both employees and members of society, in addition to strict compliance with laws, rules and regulations.

Please refer to pages 60–69 for details about corporate governance and pages 74–75 for more information on compliance.

Sharing the benefits of growth with shareholders

Our shareholder return policy is designed to maximize corporate value by sharing the benefits of medium- to long-term profit growth with shareholders, while also balancing shareholder returns with the need to continue investing in the Group's growth and in strategic business initiatives such as partnerships.

For fiscal 2018, we paid an annual dividend of ¥94 per share, an increase of ¥12 from the previous fiscal year. We have now raised the divided for seven consecutive years. Following on from fiscal 2017, we also repurchased and cancelled approximately 7.35 million shares of common stock, accounting for 2.3% of total issued shares before cancellation. In recent years, we have held treasury stock equivalent to around 3% of total issued shares, but after a review aimed at enhancing the flexible use of capital resources, we reduced our holding to 1.8% through cancellation. We plan to maintain the ratio at around 2%, aiming to increase corporate value while flexibly deploying capital. Going forward, we will continue to use our shareholder return policy to pass on the benefits of Shionogi's growth to shareholders.

Please refer to page 83 for more details about shareholder returns.

A final word

Everyone at Shionogi is fully committed to achieving the goals of SGS2020 and ensuring that the Group continues to grow after 2020, while also realizing our corporate mission globally: "To strive constantly to supply the best possible medicine to protect the health and wellbeing of the patients we serve." We will work to address various ESG issues as a company that seeks to grow sustainably contributing to a more vigorous society through improved healthcare, and we will strive to help create a sustainable society as a company that provides both corporate value and social value to stakeholders.

Isao Teshirogi, Ph.D.
President and CEO

Value creation process

The Shionogi Group tackles social issues and addresses the needs of healthcare providers through its business activities as a drug discovery-based pharmaceutical company. Shionogi also strives to grow and develop as a company that plays a meaningful role in society, sharing the benefits of growth with all its stakeholders. This is our value creation process. By sustaining this process, we aim to continue increasing the Group's various management capitals to maximize the corporate value of the Shionogi Group.

Shionogi's Management Capitals

Financial Capital

Consolidated net assets

¥672.4 billion

Human Capital

Number of employees

5,233

Intellectual Capital

Strategic business investment budget for fiscal 2018 ¥20.0 billion (max.)

R&D expenses ¥68.3 billion

Social and Relationship Capital

Building relationships of trust through cooperation with stakeholders

Manufactured Capital

Number of manufacturing facilities	Number of plants
4 facilities	3 plants

Natural Capital

Energy use

1,522,000 GJ

inputs

Changes in our business environment

- Rising population
- Aging societies in upper middle income countries
- Changes in the prevalence of certain diseases due to climate change
- Changing healthcare needs
- Advances in IT and AI technologies

Public health issues

- Deterioration in public health and welfare budgets
- Drug-resistant bacteria and viruses
- Expanding and diversifying healthcare needs

Healthcare needs

Research (Drug discovery research, CMC research) P76

Target therapeutic areas: Infectious diseases, pain / CNS disorders

Drug development P77

Marketing (Domestic business, overseas business) P80–81

Medium-Term Business Plan

Updated SGS2020 P06–07

Manufacturing P46–47

Quality management P48–49

supply chain P56

Corporate governance P60–69

Balance the needs of four stakeholder groups P70–71

Shionogi's Company Policy P03

Shionogi's Action Guidelines P03

Shionogi's Strengths / Characteristics

Continuous innovation

Creating a steady stream of revolutionary new drugs such as *Tivicay* and *Xofluza* with our SAR engine for small molecule drug discovery

P20–29 →

Expertise in infectious diseases

- More than 60 years of research experience
- Promoting proper use of medicines
- Bacteria library resources for long-term study

P22–24, 30–35 →

Resilient and efficient management

- High operating margin
- Continuous reform of cost structure and business approaches

P09 →

Various strategic partnerships

- Active use of diverse partnerships
- Flexible adjustment to contracts in line with business conditions *Crestor* and *Tivicay* ····· P05

P05, 28–29 →

Increase in management capitals (fiscal 2018)

Financial Capital

ROE ····· 20.9%

Operating margin ····· 38.1%

Dividend raised for 7 consecutive years

Human Capital

Employee satisfaction score ····· Improved from 3.91 to 3.93 (average for major Japanese companies is 3.68)

Employee turnover rate ····· 1.6%

Ratio of female managers ····· 10% (Target: 10%)

Health & Productivity Stock ····· 4 Selected for consecutive years

Intellectual Capital

Patents ····· 1,730 (As of July 31, 2019, including patent applications)

New tie-ups through strategic business investment ····· 10

Ratio of proprietary drugs ····· 69% (Target: 50% or higher)

Social and Relationship Capital

Ratio of HIV franchise drugs supplied to developing countries ····· Over 40%

Charitable donations ····· ¥45 million (Money donated to 2 disaster funds and 10 groups)

Manufactured Capital

COGs ratio ····· 15.1% (Improvement of 6.3ppt YoY)

Natural Capital

CO_2 emissions ····· Reduced by 35%

Water usage ····· Reduced by 37% (both compared with levels in fiscal 2005)

outputs

outcome

Value Created

Society

Solutions for public health issues
Supporting local communities
Creating a sustainable society

Customers

Improving quality of life (QOL)
Reliable supplies of high-quality medicines

Grow sustainably as a drug discovery-based pharmaceutical company contributing to a more vigorous society through improved healthcare

Shareholders

Constructive dialogue
Stable and sustained shareholder returns

Employees

Job satisfaction and skills improvement
Stable employment and compensation

Shionogi Group's material issues (Materiality)

Our vision in the updated SGS2020 Medium-Term Business Plan is "to grow sustainably as a drug discovery-based pharmaceutical company contributing to a more vigorous society through improved healthcare." To make that vision more tangible, we have carried out a materiality assessment to identify priority issues for the Shionogi Group. To grow sustainably as a drug discovery-based pharmaceutical company contributing to a more vigorous society through improved healthcare, we have identified and categorized material issues that matter most to Shionogi that provides value to four stakeholder groups – customers, local communities, shareholders and employees. To mark the start of Japan's new Reiwa era, we revisited the basic tenets of our business and identified material issues to help the Group refocus on the importance of growing sustainably contributing to a more vigorous society through improved healthcare.

Companies in the pharmaceutical sector and many other industries are grappling with rapid developments in the operating environment. Under those conditions, companies have to work with stakeholders to improve foresight, reduce business risk and harness their strengths to create new business opportunities that drive growth. Given that need, Shionogi has conducted dialogue with shareholders to identify material issues based on the Group's strategic direction, challenges, and demands from society. Shionogi will continue to focus on three priority material issues, while also contributing to the creation of sustainable society and driving the Company's growth by responsibly addressing and stepping up its response to various ESG issues. Based on that approach, Shionogi will make a concerted effort to be a relevant company for all stakeholder groups well into the future.

Materiality assessment process

STEP 1
Select social issues as materiality candidates

- We selected social issues through various channels of stakeholder engagement, referencing requirements in international guidelines and criteria used in assessments for socially responsible investment.

Main guidelines used as reference

Sustainable Development Goals (SDGs), GRI, ISO 26000, SASB

STEP 2
Prioritize social issues

- Led by the Corporate Strategy Division (Corporate Planning Department, Finance & Accounting Department, Corporate Communications Department), Human Resources & Administration Department, Corporate Social Responsibility Department and the Government Affairs Department, we created a materiality map to identify and categorize material issues from two perspectives – Importance to Society and Relevance to Shionogi's Business.
- Relevance to Shionogi's Business was assessed based on the updated SGS2020 Medium-Term Business Plan.

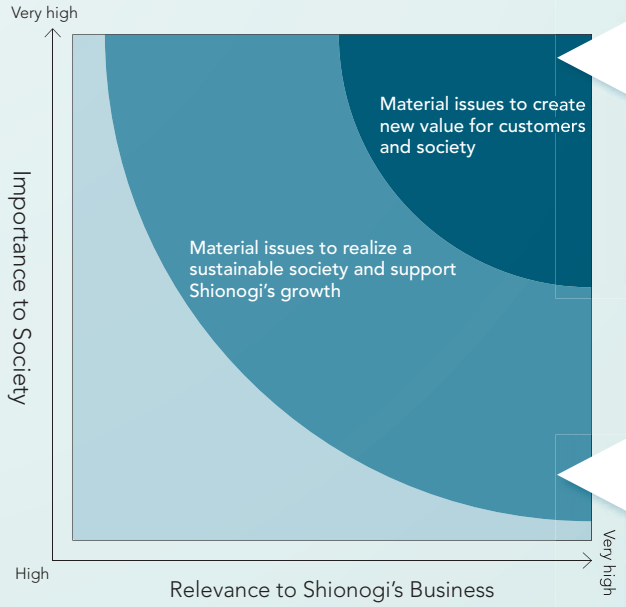
STEP 3
Conduct hearings with stakeholders

- We conducted hearings with investors, experts and other external stakeholders and with related internal departments to confirm the suitability of the materiality map.

STEP 4
Identify material issues

- Material issues were identified after discussions about the suitability of materiality by the Corporate Executive Committee and the Board of Directors
- We plan to regularly review material issues in line with revisions to business plans, progress with initiatives and changes in the social environment.

Materiality Map



Drive innovation
- Create new medicines that take into account economic efficiency in healthcare
- Actively use diverse partnerships

Protect people worldwide from the threat of infectious diseases
- Address the problem of antimicrobial resistance (AMR)
- Tackle the world's three major infectious diseases
- Promote proper use of anti-infectives

Creating a more vigorous society
- Help end suffering from pain
- Tackle psychological and CNS disorders
- Support environments for more creative and vigorous lives
- Create new value in the healthcare field

SDGs that Shionogi can help to achieve

- Improve access to healthcare
- Supply socially responsible products and services
- Secure human resources to support growth
- Respect human rights
- Reinforce supply chain management
- Protect the environment
- Strengthen corporate governance
- Ensure compliance

Dialogue with experts

As part of the materiality assessment process, we actively incorporated the views and insights of experts and other stakeholders, as well as internal feedback and hearings, to ensure our material issues reflected society's expectations and demands. During the process and checks on the suitability of materiality, we conducted dialogue with outside specialists about the future direction of our activities, receiving valuable advice based on a broad range of expertise.

Feedback from experts

Our view is that companies should conduct their business activities based on identified material issues in order to contribute to the creation of a sustainable society and develop their businesses in a sustainable way. In this case, Shionogi appears to have used an appropriate process to identify materiality.

Shionogi has identified three priority material issues – drive innovation, protect people worldwide from the threat of infectious diseases and create a more vigorous society. All three issues are extremely important for both Japan and the world, making them ideal for materiality.

Materiality enables companies to define strategies that they should focus on, but it should also be linked to concrete actions. In the next phase, materiality should be folded into specific initiatives with KPIs, guiding sustained efforts to resolve the issues. We look forward to seeing Shionogi create value that contributes to society through business activities that address material issues.

Katsuhiko Kokubu (Left)
Professor, Graduate School of Business Administration, Kobe University

Eriko Nashioka (Right)
CPA / CPTA, Representative Director, Institute for Environmental Management Accounting

Dialogue process

The dialogue process underscored our belief that Shionogi can meet the expectations of all stakeholders by providing value to society by tackling material issues. Going forward, we will disclose concrete initiatives and KPIs related to materiality to further step up our activities.

Material Issues to Create New Value for Customers and Society

The Shionogi Group has identified three priority issues it needs to create new value for customers and society – drive innovation, protect people worldwide from the threat of infectious diseases and create a more vigorous society. Leveraging our strengths as a drug discovery-based pharmaceutical company, we aim to help create a society where people can lead more creative, vigorous and healthy lives. In this section, we look at the Shionogi Group's specific initiatives and outcomes in the three priority areas.

Shionogi's Material Issues (Materiality)

		page
Drive innovation	Create new medicines that take into account economic efficiency in healthcare	P20
	Actively use diverse partnerships	P28
Protect people worldwide from the threat of infectious diseases	Address the problem of antimicrobial resistance (AMR)	P30
	Tackle the world's three major infectious diseases	P34
	Promote proper use of anti-infectives	P35
Creating a more vigorous society	Help end suffering from pain	P36
	Tackle psychological and CNS disorders	P37
	Support environments for more creative and vigorous lives	P38
	Create new value in the healthcare field	P40
S Social activities	Improve access to healthcare	Initiatives to improve access to healthcare	P44
	Supply socially responsible products and services	Ensuring quality and safety in products and services	P46
		Measures to stop counterfeit medicines	P49
	Secure human resources to support growth	Cultivating human resources to underpin competitiveness	P50
		Promoting diversity and inclusion	P52
		Protecting the health and safety of employees	P54
	Respect human rights	Respecting human rights	P55
		Ensuring the safety of participants in clinical trials	P55
	Reinforce supply chain management	Promoting CSR procurement	P56
E Environmental activities	Protect the environment	Responding to climate change	P58
		Protecting water resources	P58
		Saving resources and reducing waste	P59
		Appropriately managing chemical substances	P59
		Initiatives to protect biodiversity	P59
G Governance activities	Strengthen corporate governance	Establishing suitable corporate governance structures	P60
		Stakeholder engagement	P70
		Strengthening risk management	P72
	Ensure compliance	Strict compliance	P74
		Ensuring high ethical standards and transparency in business activities	P75

Material Issues to Create New Value for Customers and Society

Drive innovation

At Shionogi, we believe that to grow sustainably as a drug discovery-based pharmaceutical company contributing to a more vigorous society through improved healthcare is impossible without the constant pursuit of innovation contributing to the resolution of social issues. To that end, we seek to continue creating new drugs that balance innovation with healthcare affordability, by investing appropriate sums in R&D and maintaining small molecule drug discovery as a key strength while also diversifying into nonstandard peptide drug discovery and deepening collaboration with all manner of partners including the IT industry, in order to expand into new modalities and acquire entirely new technologies. If we are to meet the needs of both our customers and society as a whole and become a source of new value in the healthcare field, we think it essential that Shionogi remain committed to innovation, particularly as it applies to R&D.

Ryuichi Kiyama, Ph.D.
Corporate Officer, Vice President for Pharmaceutical Research Division

New drug creation balancing innovation with healthcare affordability

Ensuring both innovation and healthcare affordability

With many countries now grappling with the issue of a declining birthrate and aging population, the need to balance innovation with sustainable social security has become a fundamental global issue, to the extent of being taken up by the United Nations. The public is starting to push back against the argument that high prices are warranted by the innovative nature of new drugs. In our medium-term business plan, Shionogi Growth Strategy 2020 (SGS2020), we outline a vision of "to grow sustainably as a drug discovery-based pharmaceutical company contributing to a more vigorous society through improved healthcare," and on that premise we remain committed to supplying drugs that combine efficacy with a reasonable price.

In order to facilitate a focus on creating new drugs balancing innovation with affordable healthcare, we have maintained small molecule drug discovery as a key strength while also building on this platform to further strengthen our drug discovery capabilities by expanding into a new modality—that of medium molecule drugs including peptide-based therapies. In addition to being comparatively inexpensive in the manner of small molecule drugs, peptides rival antibody therapeutics in their target specificity (ensuring high potency with relatively few off-target side effects), while also having a molecular property profile enabling access to intracellular targets, which antibody therapeutics can struggle to reach.

Ensuring both innovation and healthcare affordability through small-molecule and nonstandard peptide drug discovery

	Small molecule drugs	Non-standard peptide drugs	Antibody-based drugs
Molecular weight	500 or below	500 to 2,000	Around 150,000
Specificity	Medium to high	High	High
Side effects	Few to moderate	Few	Few
Intracellular targets	Targetable	Targetable	Untargetable
Manufacturing costs	Low	Low	High

Innovation	×	Healthcare Affordability
Develop drugs with intracellular targets, which are difficult for antibody therapeutics to access		Achieve balance with healthcare affordability by reducing manufacturing costs

Focus on in-house drug discovery

Among pharmaceutical companies, some have scanty pipelines and therefore choose to supply patients with drugs licensed in from other companies. At Shionogi, though, we take a different approach. We believe that our job—and indeed our raison d'etre—is to be of use to patients by supplying them with products discovered in our pharmaceutical research and progressed right through to the stage of regulatory approval. We accordingly are focused squarely on in-house drug discovery. Over the past 14 years, we have succeeded in bringing seven proprietary drugs to market. Whereas the original pipeline ratio at most pharmaceutical companies is said to be 20–30%, we aspire to a ratio of 50–70%, and as at the end of March 2019, our original pipeline ratio was 69%. Given that our vision is to grow as a drug discovery-based pharmaceutical company, we take pride in this high ratio as we think it is indicative of our strength in in-house drug discovery.

Seven proprietary drugs launched over past 14 years

Crestor
Launch: 2005

Finibax
Launch: 2005

Tivicay
Launch: 2014

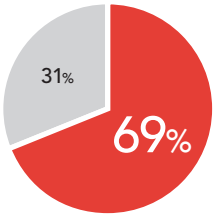
Mulpleta
Launch: 2015

Crestor OD tablets
Launch: 2016

Symproic
Launch: 2017

Xofluza
Launch: 2018

Original pipeline ratio
(As of March 2019)



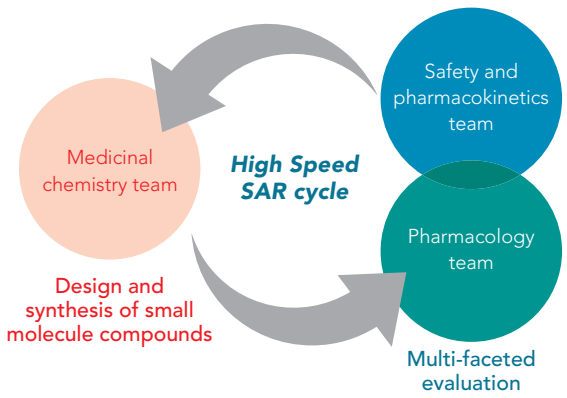
While on the one hand Shionogi is strongly committed to in-house drug discovery, on the other hand R&D into new drugs has become increasingly difficult in recent years, demanding massive resources (people, goods, money) and a lot of time. Against this backdrop, we think innovation rests not just on research and development of pipelines originated in-house, but also on collaboration with academic experts and venture companies, as well as other pharmaceutical makers. In fiscal 2018, Shionogi set a budget of ¥20 billion for strategic investments geared toward sustainable growth, with which we entered into 10 strategic collaborations.

Please refer to page 29 for details of strategic investments

Shionogi's strength in small molecule drug discovery

Capabilities in drug discovery giving rise to innovative new drugs

Shionogi's strength in research stems from our highly efficient SAR engine for small molecule drug discovery. The source of our competitiveness lies in the technological prowess of our medicinal chemistry team (responsible for design and synthesis of small molecule compounds), the pharmacology team (which performs multi-faceted evaluation of the compounds thus synthesized), and the safety and pharmacokinetics team, and in our experience in problem-solving via collaboration between the three. Through strong teamwork, we have been able to speedily and efficiently move through the SAR*1 cycle, giving rise to globally competitive, last-in-class*2 compounds such as the hyperlipidemia treatment *Crestor* and anti-HIV agent *Tivicay*, as well as the flu drug *Xofluza*, with its entirely new mechanism of action. In order to continue discovering competitive new drugs, though, we think it essential to acquire new strengths to augment the base provided by this SAR engine for small molecule drug discovery.



*1 SAR: Structure activity relationship
*2 Last in class: Unrivaled medicines with clear superiority over others that have the same mechanism of action

Shionogi's strengths in antibiotic drug discovery

Shionogi has been engaged in β-lactam antibiotic drug discovery for 30 years now, and we continue to discover new drug candidates. By combining approximately 60 years of antibiotics research with β-lactam chemistry, we have created an original platform for drug discovery that still continuously enables us to generate new drugs. In antibiotics research it is important to spend years collecting clinical isolates and analyzing their characteristics. Shionogi has amassed a considerable library of bacteria over the years, and this now constitutes a considerable advantage in our antibiotics drug discovery.

Shionogi's independent surveillance for resistant bacteria
At Shionogi, we also have spent more than 25 years conducting our own surveillance for resistant bacteria, and the data thus obtained is proving invaluable in promoting antimicrobial stewardship and AMR countermeasures.

1. Evaluate susceptibility patterns of approximately 2,500 clinical isolates of roughly 40 gram-positive and gram-negative aerobic and anaerobic strains
2. Determine MIC*1 for approximately 30 antibiotics, looking for genetic mutations in drug-resistant bacteria
3. Present results at academic symposia, also via published papers
4. The 14th bacterial strain collection initiated (as of July 2018)

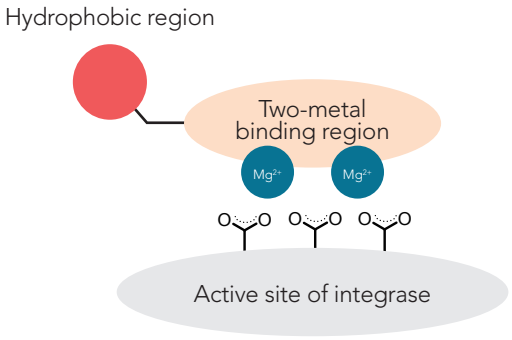
We also participated in joint surveillance programs with three academic groups*2.

*1. MIC: Minimum inhibitory concentration
*2. Japanese Association for Infectious Diseases, Japanese Society of Chemotherapy, and Japanese Society for Clinical Microbiology

Anti-HIV agent *Tivicay* leverages Shionogi's strengths in small molecule drug discovery

Shionogi's research into anti-HIV agents began in the 1980s. At the time, HIV research had not advanced far, and even if a hit compound was identified, subsequent SAR research tended not to proceed very smoothly. Against this backdrop, Shionogi identified a number of candidate compounds. In the process, we discovered a two-metal binding pharmacophore model that later played a role in the discovery of *Xofluza* as well.

In this model, both the metal binding unit and the hydrophobic unit such as benzyl moiety are important pharmacophores in integrase inhibitory activity. The compounds have inhibitory activity when the metal binding unit chelates with two metal ions coordinated by three acidic residues of the active site of integrase*3 and the hydrophobic unit is a certain distance away from the metal binding unit. We had to discontinue development of our first candidate compound owing to concerns about its safety, but then by simultaneously pursuing development of not just one but three candidate compounds, ultimately we succeeded in creating the last-in-class compound dolutegravir (brand name: *Tivicay*). This was the crystallization of a team effort, in which we never gave up no matter how many failures we encountered, and continued aspiring to ever-higher goals.



In 2016, *Tivicay* earned Shionogi the Heroes of Chemistry Award, an award given by the American Chemical Society for innovation in chemistry, and in 2017 we went on to claim the Pharmaceutical Society of Japan Award for Drug Research and Development.

*3 Integrase: Enzyme that catalyzes the integration of virally derived DNA into the host cell DNA in the nucleus

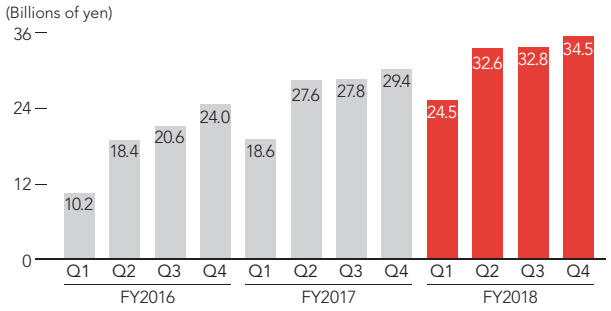
2016 Heroes of Chemistry Award for discovery of *Tivicay* (dolutegravir)

Award presentation ceremony held in August 2016
From left, Takashi Kawasuji of Shionogi, ACS President Donna Nelson, and GSK's Brian Johns

Tivicay gained regulatory approval in August 2013 in the US, in January 2014 in Europe, and in April 2014 in Japan. Our HIV franchise*1 of dolutegravir-based drugs posted global sales of £4,420 million in fiscal 2018, and continues to grow.

*1 HIV franchise: anti-HIV agent *Tivicay* and the dolutegravir combination drugs *Triumeq* and *Juluca*

Quarterly royalty income from HIV franchise



Researcher's voice

Tomokazu Yoshinaga, Ph.D.

Infectious diseases & Immunity Division
Drug Discovery & Disease Research Laboratory
Pharmaceutical Research Division

For Shionogi researchers, the discovery of *Tivicay* represents a great success story, as *Tivicay* is highly potent, has not caused any drug-resistant viruses, has few side effects, can be administered without regard to meals, and has almost no drug/drug interactions. *Tivicay*'s discovery also led to the discovery of *Xofluza*. Talking to patients at international academic symposia, though, we have been made keenly aware of these patients' grave fears about developing side effects that would force them to discontinue medication. This has instilled in us the realization that there is always room for improvement in HIV medications. While it is proving difficult to discover compounds to partner with *Tivicay* in a single-tablet regimen without affecting *Tivicay*'s efficacy, we are working as one to discover a suitable partner as expeditiously as possible, by combining the SAR engine for small molecule drug discovery that is our core strength with innovative ideas. In the knowledge that daily pill-taking is a chore for many, we are working also on a long-acting formulation for injection every three months, all the while also persisting in our search for an HIV cure.

Tivicay
Launch in Japan: Apr. 2014

Triumeq
Launch in Japan: Apr. 2015

Juluca
Launch in Japan: Dec. 2018

Dovato
Launch in the US: Apr. 2019

Past and future of Shionogi's R&D into anti-HIV agents

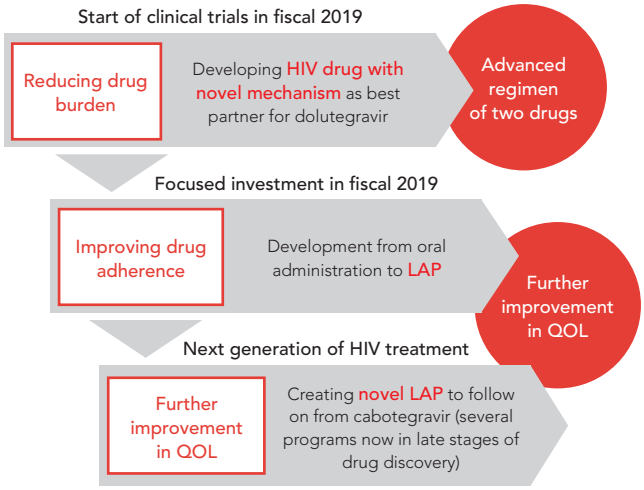
While on the one hand people are now living longer with HIV, they must spend a lifetime taking drugs to suppress the virus. There is a need to improve QOL by exposing newly diagnosed HIV patients to fewer drugs at the start of treatment, thereby alleviating side effects and reducing dosing frequency.

There is now a mountain of clinical data regarding *Tivicay*, demonstrating both potent antiviral activity and a high barrier to resistance. Use of *Tivicay* as the key drug has made it possible to develop two-drug combinations as an alternative to the standard treatment regimen of three or more drugs, resulting in the launch in recent years of *Juluca* (dolutegravir + rilpivirine) and *Dovato* (dolutegravir + lamivudine).

Based on favorable results from Phase III trials, regulatory applications have been submitted in the US and Europe for use of Shionogi's proprietary anti-HIV drug candidate cabotegravir in combination with rilpivirine, as a monthly injectable treatment (long-acting parenteral formulation, or LAP) for HIV. In these trials, patient preference data showed that a majority of participants preferred the LAP over daily therapy. Cabotegravir also is under study for HIV prevention, for which there is clearly a public health need, and as such is expected to offer a new option for both the treatment and prevention of HIV.

We believe that Shionogi carries a responsibility to continuously come up with new treatment options as a means of further improving QOL for people living with HIV, while also preparing for the potential emergence of resistance to *Tivicay*. On that premise, we already have discovered a new anti-HIV drug candidate with a novel mechanism of action, and we are furthermore focusing on research into an HIV cure.

Leveraging experience in developing HIV drugs with novel mechanism in formulation of LAP



Platform for continuous generation of new drugs: Now applying drug discovery know-how to research into flu drugs

The development of *Tivicay* began with a Shionogi researcher's findings concerning the active site binding of HIV integrase. This unique discovery triggered the start of internal competition to synthesize a new superior family of compounds, with the commitment of our research team ultimately leading to the creation of *Tivicay*. This also prompted us to go ahead with research regarding the cap-dependent endonuclease enzyme within the influenza virus, based on the idea of similar binding behavior. Our research team, confident that the science in HIV integrase inhibitors could be adapted for cap-dependent endonuclease inhibitors, took their know-how from *Tivicay* in a new direction, resulting in the discovery of *Xofluza*. This illustrates how passing on expertise and internally cultivating both human resources and technology is a key part of our approach to small molecule drug discovery at Shionogi, constituting a solid foundation for our drug discovery platform.

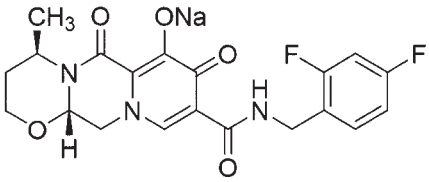
Novel flu drug *Xofluza* has revolutionary mechanism of action

Shionogi launched the novel flu drug *Xofluza* in Japan on March 14, 2018. A cap-dependent endonuclease inhibitor originated by Shionogi, *Xofluza* suppresses the replication of influenza viruses by a mechanism different from existing flu drugs. As *Xofluza* is an oral tablet requiring only a single dose, it is expected to improve compliance as well as convenience, and contribute to improving QOL for patients suffering from influenza.

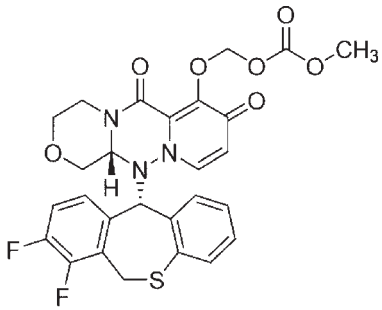
Roche plans to take a leading role in developing and marketing the drug globally, except for Japan and Taiwan. We believe that partnering with Roche will enable us to hasten delivery of *Xofluza* to patients around the world.

Tivicay

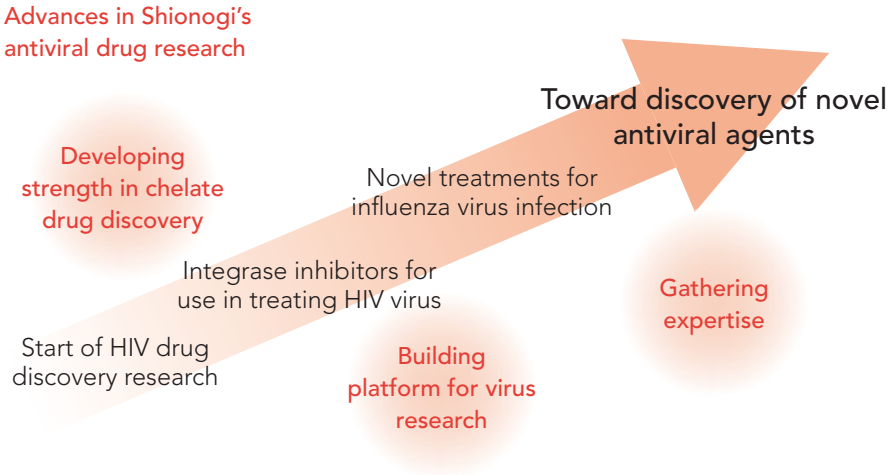
- HIV integrase inhibitor
- Potent activity and high barrier to development of resistance



Xofluza



Antiviral drug research x original compound design



Peptide drug discovery

Shionogi currently is engaging in nonstandard peptide drug discovery as a new modality offering potential synergies with our existing strength in small molecule drug discovery. We previously have had peptide drug candidates that were in-licensed from other companies, but now we plan to undertake our own peptide drug discovery research.

(1) Use of PDPS drug discovery platform to enhance drug discovery efficiency

In February 2016, Shionogi entered into a joint research and development agreement with PeptiDream Inc., with a view to utilizing the latter's proprietary Peptide Discovery Platform System (PDPS) to identify nonstandard cyclic peptides against multiple drug discovery targets. Nonstandard peptides are expected to reduce side effects, given their high affinity and selectivity for specific intracellular and extracellular targets. In June 2017, Shionogi went on to become the first Japanese company to enter into a non-exclusive license agreement for the use of PDPS. Under this agreement, we have taken on new joint R&D projects with PeptiDream, and accelerated innovation by bringing together the strengths of both companies.

Nonstandard cyclic peptides

- Quick screening, with low costs and small tasks
- Generates highly selective and highly active peptides
- Hits can be acquired even for challenging targets

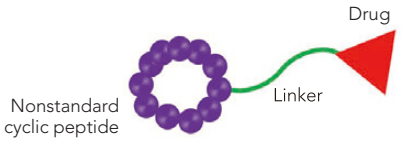
(2) PeptiStar Inc., a CMO*1 specializing in nonstandard peptides

Currently, no country in the world is home to a CMO that can stably provide high-quality peptide APIs at low cost. With this in mind, Shionogi, PeptiDream and Sekisui Chemical inked a joint venture accord in August 2017 to establish PeptiStar, Inc. to engage in research and development, manufacturing, and sales of peptide APIs, in the view that a new CMO possessing specialized technology for peptide therapeutics could help expand the market for these drugs. This joint venture is the world's first CDMO*2 to engage in research and development and manufacturing of a broad range of peptide APIs, from standard peptide APIs to nonstandard peptide APIs with a cyclic structure incorporating non-natural amino acids, and it aims to provide stable supplies of high-quality peptide APIs at low cost. Japan leads the world in peptide drug discovery, and it is expected that this new venture will bring together expertise and know-how from across Japan to create a CDMO specializing in this area, underpinned by the knowledge and technologies related to nonstandard peptide drugs possessed by PeptiDream. PeptiStar will be capable of manufacturing at least 100 kilograms of peptide APIs annually, more than any other company in Japan. Peptide therapeutics are cheaper to manufacture than antibody drugs, and by commercializing peptide manufacturing we seek to strike a balance between innovation in drug discovery and costs.

PeptiStar

(3) Using PDCs*3 to strengthen our presence in the CNS area

In January 2019, Shionogi entered into a joint venture agreement with PeptiDream for the discovery and development of peptide drug conjugates (PDCs). Shionogi is active in drug discovery for CNS indications, and as this technology improves the migration of drugs to the brain, we expect it to add to our strengths in this area.



*1 CMO: Contract Manufacturing Organization
*2 CDMO: Contract Development and Manufacturing Organization
*3 PDC: Peptide Drug Conjugate. A conjugate that connects a drug and nonstandard cyclic peptide with a linker. This joint research aims to establish a new approach to discovering drugs targeting the brain, through the discovery of nonstandard cyclic peptides that can pass through the blood-brain barrier.

Discovery story for *Xofluza*, a drug capitalizing on group value chain

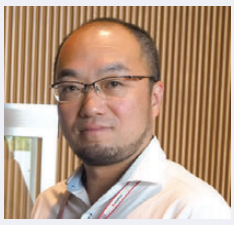
抗インフルエンザウイルス剤
ゾフルーザ®
XOFLUZA®

Promptly providing medicine to those in need through value chain evolution

Xofluza is an innovative new drug designated under the Sakigake scheme for accelerating the approval process. Through a concerted effort to deliver this product to patients even one day sooner, the Shionogi Group succeed in gaining approval for and launching *Xofluza* within roughly three years of commencing Phase I trials. If Shionogi is to continue advancing innovation and growing as a drug discovery-based pharmaceutical company, we think it essential that all value chain actors not only play their own roles, but also pull together to promote evolution of the value chain as a whole.

Research

Innovative new drug discovery in the infectious disease area is Shionogi's strength



Takao Shishido

Drug Discovery &
Disease Research Laboratory

Even before the discovery of the HIV integrase inhibitor, researchers recognized the structural similarities between HIV integrase inhibitors and cap-dependent endonuclease inhibitors, forming the belief that if HIV integrase inhibitors were brought to market, the science could be adapted for cap-dependent endonuclease inhibitors. However, when it actually came to deployment in other programs of the chelate drug discovery know-how gained from *Tivicay*, many things did not go as expected, leading to much trial and error. Some programs even needed to be suspended halfway, so it came as something of a shock when I observed binding of our seed compound*1 to the active center of cap-dependent endonuclease.

*1 Compound found in early screening to have certain level of activity against drug discovery target

Makoto Kawai

Medicinal Chemistry Research
Laboratory

When problems became evident with our first drug candidate, and the realization came that development could go no further, I was the only person left out of a team once composed of several researchers. I was shattered and didn't think I could go on, but I was urged not to quit and took up the challenge again, resulting in *Xofluza*. The active form of *Xofluza* has a chemical structure that is highly unusual in medicinal chemistry, in order to heighten its efficiency. That we were nonetheless able to create *Xofluza* is testament to our researchers' never-failing passion, innovative ideas and chemical knowledge base.

CMC

CMC technologies led to design and development of optimal formulation

Project members

In order to complete development in as short a time as possible, work on finding the optimal formulation proceeded at unprecedented speed. Not all activities were successful, and we experienced disappointments. Nonetheless, when tablets of an unplanned strength were required during clinical development, we were able to supply the investigational medicinal product (IMP) three to six months earlier than usual. At the manufacturing stage, too, we were able to keep the technology transfer period 11 months shorter than normal. Facing the pressure that failure would not be tolerated, members of the IMP Manufacturing Center were involved in the establishment of a small-scale commercial manufacturing process at the Settsu Plant, and this allowed a smoother shift to commercial manufacturing. In this manner, CMC personnel took on the strategic challenge of minimizing the product development period, thereby bringing the best conceivable drug to market in the shortest possible time.

Development

Global development also completed in quick time

Takeki Uehara
Global Project Leader

Kenji Tsuchiya
Project Manager

Undeterred by difficulties, the project team worked tirelessly to come up with the best strategy that would enable us to launch the drug in fiscal 2017, so that we could fulfil our mission of delivering *Xofluza* to patients as soon as possible. The development schedule called for *Xofluza* to launch within roughly three years of clinical trials commencing, and to that end it made full use of the influenza season every year. Starting Phase III studies in the season following completion of Phase II studies was quite a challenge and likely appeared nearly impossible, as did completion of the global Phase III study with about 1,500 enrollments in a single season. In the global trial in particular, a single mistake could lead to major delays, especially if a flu season was missed, so the team worked together to cover each task, going beyond national borders, divisions and roles to make sure there were no blunders. I think that the secret to our success was strong teamwork. The team shared the same goal and played their roles in a cooperative spirit based on mutual trust, enabling them to work together as a single unit. Members of other projects also cooperated on all fronts to make *Xofluza* a success, so our achievements were really due to everyone's strengths, not just to those of *Xofluza* project members.

Japan has the highest standard of influenza treatment in the world, built on early diagnosis and treatment. Shionogi's next mission is to take this impressive level of treatment to the rest of the world and reduce, if even by one, the number of people who become ill and die of influenza—a serious problem all over the world.

Regulatory affairs

Approval in first round of Sakigake designation system for pharmaceutical products

Yuko Kinoshita
Regulatory Affairs Department

Hitomi Ikemoto
Regulatory Affairs Department

Under the Sakigake designation system, the process from filing to approval takes six months or less, as there already has been a prior assessment consultation process. In 2015, applications were received for over 50 drugs in the first round of the Sakigake designation system. *Xofluza* received Sakigake designation in the expectation that it would prove efficacious in patients at high risk of complications, such as the elderly and children, and this focused the public's attention on the drug. Even for drugs with Sakigake designation, though, the requirements are the same as for drugs undergoing the normal process, in terms of the documentation needed to support filings for manufacturing and marketing approval, and the aspects screened by authorities. For this reason, shortening the review period hinges on finding solutions ahead of time to issues deemed likely to be raised by the regulators. This required us to quickly reach a mutual understanding with the authorities and address potential issues without delay. In order to realize our goal of bringing *Xofluza* to the world as soon as possible, we pulled together as a team and achieved Shionogi's maiden approval under the Sakigake designation system.

Active use of diverse partnerships

At Shionogi, we think sustainable growth hinges not only on new drug creation, but also on consolidating our strengths in areas of strategic focus. In this era of diversifying healthcare needs, there seems to be risk in having both a great deal of infrastructure and not much infrastructure. To maintain large infrastructure, it is necessary also to keep a bulging pipeline. However, this adds to the volume and type of work that in theory should be performed in-house. Through external partnerships, we seek to enhance overall productivity through collaboration in areas where it would be difficult for us to go it alone. By keeping our head office functions comparatively lean while at the same time retaining certain strengths in this ever-changing world, we aim to stay nimble and ensure that our presence is felt.

Strategic alliances geared toward sustained growth after 2020

While Shionogi will continue to develop pipeline projects created in-house, we think expansion of pipeline projects and technologies through alliances also is essential for driving innovation. In order to flesh out our product pipeline over the medium and long term, in fiscal 2018 Shionogi set aside a special budget of ¥20 billion for strategic R&D investment in addition to ordinary R&D expenses, and entered into a number of strategic business alliances.

In the field of infectious diseases, Shionogi traditionally has focused on HIV, influenza virus, and multidrug-resistant bacteria. In recent years, though, we have expanded the scope of our research to include the three major infectious diseases (HIV as well as tuberculosis, and malaria) and intractable infectious diseases. To that end, we have in-licensed research assets geared toward accelerating our research into the three major infectious diseases, while also investing in entirely new technologies for the treatment of intractable infectious diseases.

In the pain/CNS area, we have in-licensed assets that should enable us to provide a broader range of treatment options, thereby fleshing out underpopulated portions of our pipeline. We also have expanded into new modalities in order to address medical needs that have not been met by small molecule drugs, acquiring new technologies that will further our research into medium molecule drugs.

Against this backdrop, we plan to harness our competitive edge in small-molecule drugs and develop an order of priority for investment of our limited resources, in order to achieve ongoing improvement in R&D efficiency, both in-house and at partner companies. To further contribute to better health through the use of IT, we look to deepen our collaboration with the IT sector and other industries, tackling new modalities including digital therapeutic apps. In this manner, we aim to provide patients with an increasingly diverse range of treatment options.

Strategic Business Investments

Infectious Disease	Drug candidates for mycobacterial diseases (Hsiri Therapeutics) Research collaboration on anti-RS virus agent (Ube Industries) Collaborative research on prophylaxis and treatment of malaria(Nagasaki University) Nitric oxide inhaled antimicrobial drug candidates (Vast Therapeutics) Technology for antimicrobial resistance (Nemesis Bioscience)	Research on the 3 major infectious diseases (HIV, Tuberculosis, Malaria) and refractory infectious diseases ➡ Establish Shionogi's presence in infectious diseases globally
Pain CNC	Antidepressant candidate S-812217(Sage Therapeutics) Drug candidate for cognitive and memory deficits BPN-14770(Tetra Discovery Partners) Digital therapeutics AKL-T01, AKL-T02(Akili Interactive)	Expanding into wider range of treatment options ➡ Provide new treatment options with novel mechanisms
Modality	PDC technology (PeptiDream) Regenerative medicine product candidate ADR-001 (Rohto Pharmaceutical)	Acquiring new modalities ➡ Solve unmet needs that cannot be met with small molecule drug

Entered into 10 new strategic partnerships with view to sustained growth after 2020

Protect people worldwide from the threat of infectious diseases

As a drug discovery-based pharmaceutical company, we must ask ourselves what Shionogi can do for society. One answer springs to mind, and that is "freeing people from the threat of infectious diseases." Throughout history, mankind has been under constant threat from infectious diseases. No sooner is a new agent introduced than the pathogen develops resistance to it; this has been a persistent battle that continues today. As globalization gathers pace, borders are becoming more porous and people are able to move freely around the world, creating an urgent need for pandemic preparedness. At a time when other large pharmaceutical companies have moved away from the infectious disease area, I believe it is incumbent on Shionogi to maintain and further develop this particular strength, not just in the treatment of infectious diseases, but also in their prevention and diagnosis.

Takuko Sawada
Director,
Executive Vice President

Deaths attributable to AMR per year by 2050, if no action is taken
More than **10 million**

Estimated economic impact
$100 trillion

Address the problem of antimicrobial resistance (AMR)

A significant unmet need: "Time is running out"

Antimicrobial resistance (AMR) is a real and immediate global threat.

The damaging effects caused by resistant bacteria are already responsible for an estimated 700,000 deaths per year globally, and future projections of the impact of unresolved AMR surpass the projected number of deaths caused by cancer by 2050. As AMR also could have a grave impact on the global economy, it potentially could pose a high direct and indirect cost to society.

In the future, lack of effective antibiotics could make routine medical interventions extremely dangerous or even impossible.

For these reasons, AMR must be regarded as a global, regional, and national priority for health organizations and governments, to be addressed with the utmost urgency on a global scale.

WHO and United Nations Initiatives to Tackle AMR

WHO Global Action Plan

- **Global cooperation spearheaded by World Health Assembly**
- **Global Action Plan setting out five strategic objectives**

1. Improving awareness and understanding of antimicrobial resistance
2. Strengthening the knowledge and evidence base through surveillance and research
3. Reducing the incidence of infection through effective sanitation, hygiene and infection prevention measures
4. Optimizing the use of antimicrobial agents in human and animal health
5. Developing an economic case for sustainable investment

United Nations High-Level Meeting (September 2016)

- World leaders signaled an unprecedented level of attention to curb the spread of multidrug-resistant infections.
- Countries reaffirmed their commitment to develop national action plans on AMR.
- Leaders recognized the need for stronger systems to monitor drug-resistant infections and the volume of antimicrobials used in humans, animals and crops, as well as increased international cooperation and funding.
- Leaders also called for new incentives for investment in research and development of new, effective and affordable medicines, rapid diagnostic tests, and other important therapies to replace those that are losing their power.

Combating worldwide public health challenge of AMR

The reality is, though, that many pharmaceutical companies have moved away from infectious disease area, as despite being a public health challenge of utmost importance, from a business perspective this is an area in which profits are hard to come by. Not only is it becoming more and more difficult to conduct R&D into new antibiotics, but also initiatives that restrict the use of new antibiotics have led to uncertainty around market size. It has been reported that only five of the world's top 50 pharmaceutical companies currently have an antibiotics pipeline.

Against this backdrop, Shionogi has made an on-going commitment to the R&D of new antimicrobial therapies, and we will vigorously pursue such activities to ensure that both patients and society as a whole will benefit from new antibiotics.

SGS2020 identifies "Protecting people from the threat of infectious diseases" as one of major social issues we should address, and declares that Shionogi will remain committed to developing new drugs against infectious diseases that lack effective medical treatments, and to promoting antimicrobial stewardship. In 2018, we published the Shionogi AMR Position Paper detailing our point of view and efforts in this regard, and we will continue driving forward our commitment to becoming a leading company in the fight against AMR, by promoting antibiotic R&D, proper use, and access to antibiotics.

Detailed information on Shionogi AMR Position Paper
http://www.shionogi.co.jp/en/company/csr/activities/amr.html

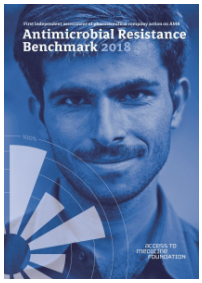
Long-term commitment to improving R&D to provide novel treatments for infectious diseases

Shionogi's involvement in the field of infectious diseases essentially began when we began importing streptomycin in the years following World War II. Subsequently, we commenced sales of *Ilotycin* (licensed in from Eli Lilly) in 1952, and in 1959 we launched the long-acting sulfonamide *Shinomin*, the first proprietary product to come out of our research. The drug was out-licensed to Roche, helping to treat patients with infectious diseases worldwide. We also released the sulfamethoxazole and trimethoprim combination *Baktar*, which is still widely used by patients worldwide. Shionogi now has been involved in infectious disease R&D for over 60 years, either independently or via strategic alliances with other companies/organizations, and we seek to continue generating new products in this field by drawing on that extensive experience in antibiotic drug discovery.

At Shionogi, we also have spent more than 25 years conducting our own surveillance for resistant bacteria, and the data thus obtained is proving invaluable in promoting antimicrobial stewardship and AMR countermeasures.

Shionogi's efforts to combat AMR also have been recognized externally. In a recent Antimicrobial Resistance Benchmark 2018 survey, Shionogi was the only Japanese pharmaceutical company to qualify for inclusion, and was recognized along with the seven other large research-based pharmaceutical companies. Especially, Shionogi was highly recognized in the survey as having the highest annual ratio of investment in R&D for anti-infectives of any of the companies surveyed (based on investment as a proportion of net sales).

Shionogi is also active in the field of antiviral treatments. Over the years we have released a number of innovative anti-infectives including the anti-HIV agent *Tivicay* and related pipeline drugs, and the flu drug *Xofluza*.



Antimicrobial Resistance Benchmark 2018

Please refer to page 22 for details of Shionogi's strength in antibiotic drug discovery, and its independent efforts in surveillance for resistant bacteria.

Shionogi and Industry Efforts to Combat AMR

Shionogi also actively participates in various national and international initiatives addressing AMR, as a means of contributing to global resolution of this public health challenge.

Davos Declaration (January 2016)

- **Declaration by the pharmaceutical, biotechnology and diagnostics industries on combating antimicrobial resistance**
- **Signed by more than 100 companies, including Shionogi, who committed to:** work to reduce the development of antimicrobial resistance; invest in R&D that meets global public health needs with new innovative diagnostics and treatments; improve access to high-quality antibiotics and ensuring that new ones are available to all; and remove financial incentives that reward the prescribing of antibiotics in greater volumes.

Industry Roadmap for Progress on Combating Antimicrobial Resistance (September 2016)

Signed by 13 major global pharmaceutical companies, including Shionogi, and laying out a roadmap for four key commitments:

acting on environmental pollution associated with antibiotic manufacturing;
supporting improved stewardship of antibiotics;
facilitating improved global access to antibiotics; and
supporting open collaboration between industry and public researchers.

AMR Industry Alliance Board

Seven pharmaceutical companies—Shionogi, Pfizer, Merck, Johnson & Johnson, GlaxoSmithKline, Sanofi, and Roche—form the Board of the AMR Industry Alliance, a coalition of over 100 research-based pharmaceutical, generics, biotechnology and diagnostics companies committed to slowing the spread of AMR and promoting industrywide advances in life sciences.

Stimulating Research and Development of New Antibiotics

Various initiatives to stimulate sustained investment by the public and private sectors in R&D into antibiotics

Push & Pull Incentives

Push-type: Provision of financial support for R&D

▷ Includes CARB-X, GARDP, IMI, JPIAMR, NIH/NIAID and BARDA

Pull-type: Reward for innovation through funding that will enhance return on investment (ROI) and improve the accuracy of demand forecasting

▷ In recent years, the G20 has acknowledged the importance of such incentives, debating whether or not to introduce a market entry reward.

WHO List of Antibiotic-Resistant "Priority Pathogens"

On February 27, 2017, the World Health Organization (WHO) published its first-ever list of antibiotic-resistant "priority pathogens," a catalog of 12 families of bacteria that pose the greatest threat to human health. Stating that "Antibiotic resistance is growing, and we are fast running out of treatment options," the WHO stressed the need to develop new antibiotics. The 12 pathogens on the list are divided into three categories according to the urgency of need for new antibiotics, with carbapenem-resistant bacteria slotting into the critical category where the need for new antibiotics is considered particularly urgent.

WHO Priority Pathogens List for R&D of New Antibiotics

Critical Priority	
Acinetobacter baumannii	carbapenem-resistant
Pseudomonas aeruginosa	carbapenem-resistant
Enterobacteriaceae	carbapenem-resistant

Cefiderocol shows potent antibacterial activity against these three pathogens

High Priority	
Enterococcus faecium	vancomycin-resistant
Staphylococcus aureus	methicillin-resistant vancomycin-resistant
Helicobacter pylori	clarithromycin-resistant
Campylobacter	fluoroquinolone-resistant
Salmonella species	fluoroquinolone-resistant
Neisseria gonorrhoeae	cephalosporin-resistant fluoroquinolone-resistant

Medium Priority	
Streptococcus pneumoniae	penicillin-non-susceptible
Haemophilus influenza	ampicillin-resistant
Shigella species	fluoroquinolone-resistant

Prepared by Shionogi, based on WHO press release

Development of cefiderocol

Many of the pathogens in the critical category (deemed in the most urgent need of new R&D) are resistant to carbapenem-type antibiotics, and drugs effective against these pathogens are in high demand worldwide. Shionogi is developing cefiderocol as a candidate for the treatment of multidrug-resistant gram-negative bacterial infections, and we believe it could evolve into a valuable weapon in the fight against the three carbapenem-resistant pathogens positioned by the WHO as the highest priorities.

Clinical trials with a view to gaining approval are proceeding as planned—including a Phase III study in carbapenem-resistant gram-negative bacterial infection and another Phase III study in nosocomial pneumonia—and applications have been filed in the US and Europe.

Shionogi remains fully dedicated to tackling the global public health threat of AMR.

New initiatives for hard-to-treat bacterial infections

Looking ahead, Shionogi's strategy for AMR drug discovery will be to continue research into small-molecule anti-infectives targeting multidrug-resistant bacteria, while also expanding our horizons to include research into hard-to-treat bacterial infections.

To that end, in fiscal 2018 we made strategic investments in companies possessing entirely new modalities for the treatment of hard-to-treat bacterial infections. By combining our alliance partners' unique strengths with our own knowledge and experience in small molecules and infectious diseases, we aim to discover new therapies that would be beyond the scope of other companies.

Please refer to page 29 for details of our strategic investments in fiscal 2018.

Nemesis Bioscience Ltd.

A technology to inactivate antibiotic-resistant genes by weaponizing bacteriophages with CRISPR-Cas genome-editing technology

▷ A new approach to treatment that regains sensitivity to antibiotics in drug-resistant bacteria

Vast Therapeutics

A technology to manufacture drug formulations to stably and continuously emit nitric oxide, which has broad-spectrum antibacterial activity

▷ Toward a new treatment approach for respiratory infections

Tackle the world's three major infectious diseases

The three major infectious diseases (HIV/AIDs, tuberculosis and malaria) constitute a grave threat and massive challenge from the perspective of global health. Swiftly halting the spread of these diseases is an important theme of the United Nations' Sustainable Development Goals (SDGs). Shionogi's strategic investments in fiscal 2018 also included the in-licensing of research assets with potential to accelerate drug discovery, with a view to helping beat these three major infectious diseases.

Please refer to page 29 for details of our strategic investments in fiscal 2018.

HIV

Shionogi has contributed greatly to the treatment of HIV through the discovery of *Tivicay* (dolutegravir), an HIV integrase inhibitor that has high levels of efficacy and safety and minimal risk of drug resistance. Currently, US, European and domestic HIV treatment guidelines recommend *Tivicay* as one of the first-line drugs for treatment-naïve patients, making it an important new treatment option for all HIV positive patients.

Although HIV treatment has come a long way, there remains a need for further improving patients' quality of life (QOL) by exposing them to fewer drugs and reducing dosing frequency. With a view to meeting these unmet needs, Shionogi is supplementing research work already under way with a focus on long-acting parenteral (LAP) formulations and realizing a cure for HIV.

Please refer to pages 22–23 for details of R&D into *Tivicay*, and our future plans for HIV research.

Tuberculosis and non-tuberculous mycobacterial (NTM) diseases

Each year, more than 10 million people reportedly fall ill with tuberculosis, and co-infection with HIV is another significant public health issue. Shionogi is actively engaged in addressing these challenges, by such means as licensing in the anti-tuberculous drug candidate S-004992 from China-based C&O Pharmaceutical Technology, as well as research assets from Hsiri Therapeutics.

Hsiri Therapeutics, Inc.

In the tuberculosis area, Shionogi has started joint research with Hsiri Therapeutics, which has an asset of small molecule lead compounds with a novel mechanism of action and extremely potent activity to mycobacteria. By entering into external alliances in this manner, we seek to pursue drug discovery targeting both tuberculosis and non-tuberculous mycobacterial (NTM) diseases.

Malaria

Along with HIV/AIDs and tuberculosis, malaria is one of the three major infectious diseases. Although it is most prevalent in tropical and subtropical regions, there are reports that malaria distribution has been altered by global warming and other aspects of climate change, potentially leading to an increase in infections. Shionogi started joint research with Nagasaki University, to form the core of a new open innovation base for industry-academia collaboration both inside and outside Japan, and establish a platform aimed at eradication of malaria.

Nagasaki University

The idea is to combine the malaria research assets and network of Nagasaki University, which has a worldwide presence in emerging and re-emerging infectious diseases, with Shionogi's expertise in small molecule drug discovery, to engage in world-class malaria research. There are plans also for Shionogi and Nagasaki University to form the core of a new base for open innovation incorporating external institutions with a range of technologies.

Promote proper use of anti-infectives

Initiatives to promote proper use of medicines

By promoting the proper use of anti-infectives, Shionogi works constantly to prevent the emergence of new drug-resistant bacteria and viruses, and to ensure that patients can continue to receive treatment, both now and in the future.

In our sales activities, Shionogi does not remunerate sales staff based on sales volume of antibiotics, as highly recognized in the Antimicrobial Resistance Benchmark 2018 survey. We expect that delinking of sales volume from revenue reward will support more proper use over the long term, leading to better patient outcomes and improving antibiotic sustainability.

In manufacturing antibiotics, Shionogi is working to reduce environmental burden.

In addition to promoting proper use of antibiotics, Shionogi

supports global and national action plans to conduct more timely and coordinated surveillance for resistant bacteria. We organize and provide relevant information to promote proper use and stewardship of antibiotics, by such means as conducting surveillance programs aimed at gathering accurate epidemiological data, and rigorously analyzing industry guidelines.

In order to promote proper use of our flu drug *Xofluza*, we also have been assiduously conducting further analysis on mutant viral strains and drug safety, and making our findings public.

Please refer to pages 58–59 and our EHS Report for details of Shionogi initiatives to reduce environmental burden as an antibiotics manufacturer.
http://www.shionogi.co.jp/en/company/csr/activities/environment.html

Public awareness and education programs

To promote proper use of anti-infectives, it is absolutely essential to conduct awareness-raising and educational activities that result in the understanding and spread of correct information concerning the prevention and control of disease and infection. Shionogi is actively engaging in such activities.

In an industry-government-academia collaboration geared toward combatting infectious diseases in children under five years of age, in fiscal 2018 Shionogi hosted a total of five seminars (attended by 339 nursery school operators and staff), to raise awareness about the MHLW's "Infection Control Guidelines for Nurseries," as revised in 2018. As a means of raising awareness among the general public as well, Shionogi has created a video explaining the guidelines and a website (Kodomo Kansensho Navi) to help parents navigate the subject of infectious diseases in children.

Shionogi also invited experts from across Japan and Asia to attend the SHIONOGI Infectious Disease Symposium 2019 for a discussion of AMR countermeasures in each country. Our aim in doing so was to broaden engagement in efforts to address the threat of AMR, and promote international cooperation.

Broadcast of Shionogi-sponsored program, Kansensho TODAY, on Radio NIKKEI

感染症TODAY

Targeted at medical professionals, this program seeks to convey a broad range of knowledge concerning infectious diseases by enlisting the aid of specialists to delve into the latest topics and offer educational content. In order to reach as many people as possible, the program keeps a library of past broadcasts to enable relistening.

Initiatives to combat neglected tropical diseases (NTDs)

Neglected tropical diseases (NTDs) such as leishmaniasis and Chagas disease also continue to threaten lives, particularly in developing countries. There has been limited progress, though, in developing effective antibiotics, giving rise to an international public health problem. Shionogi has been working with partners with various expertise in the healthcare area to find workable solutions to the numerous unmet needs in infectious diseases, and are applying the same approach to NTDs.

Contributing to the GHIT Fund*1

Shionogi has been a contributor to the Global Health Innovative Technology Fund (GHIT Fund) since it was founded in 2013, as Japan's first public-private partnership. In addition to contributing to the GHIT Fund, we also have received funding. Under the auspices of the fund, Shionogi is actively working to eliminate the threat not just of NTDs but infectious diseases in general, including by taking part in a program to discover candidate compounds to treat leishmaniasis and Chagas disease.

Participation in DNDi*2 drug discovery consortium

Together with several other pharmaceutical companies, Shionogi has been a participant in the DNDi's "Neglected Tropical Diseases Drug Discovery Booster" consortium since its establishment in 2015.

This consortium is an attempt to accelerate drug discovery for the world's most neglected diseases—leishmaniasis and Chagas disease—and also reduce associated costs. The consortium has started several screening projects for the parasites that cause leishmaniasis and Chagas disease, and most have discovered promising compounds with improved antiparasitic effects. Already, each project has reduced the costs of synthesizing compounds by tens of thousands of dollars and shortened the drug discovery period by roughly 50–70%. In recognition of these achievements, the consortium received the DNDi Project of the Year Award for 2016.

*1 GHIT Fund: Established to support R&D into revolutionary new drugs to fight infectious diseases in developing countries
*2 DNDi: Drugs for Neglected Diseases initiative

Material Issues to Create New Value for Customers and Society

Creating a more vigorous society

Among the social challenges that Shionogi seeks to address, one is the "creation of a more vigorous society." New drugs and other medical advances have extended average life expectancy around the world, but we still see room for improvement from the standpoint of healthy life expectancy. For example, we seek to help those with chronic pain (against which earlier drugs did not have sufficient analgesic effect) to lead more active lives. We also seek to relieve patients, their families, and friends from the impact of psychiatric/nervous system disorders and restore fuller participation in society. These aspirations inform many aspects of our daily activities.

Yoshiaki Kamoya
Senior Executive Officer

Help end suffering from pain

Helping to alleviate cancer pain over a period of 30 years

Back in the late 1980s when the WHO released its cancer pain treatment guidelines, prescription narcotics (opioid pain relievers) for cancer pain were not widely used in Japan. Shionogi already was supplying drugs for pain relief, and we received a request from the then Ministry of Health and Welfare to develop prescription narcotics. This proved to be a major turning point for Shionogi in the area of pain relief. In line with our Company Policy of striving constantly to supply the best possible medicine to protect the health and wellbeing of the patients we serve, we took on the development of MS *Contin* tablets, which we launched in 1989. In the 30 years since then, Shionogi has worked in tandem with regulatory authorities, academia, and medical professionals, to promote the proper use of palliative care and cancer pain relief. In recent years, we have launched *Symproic* tablets for the alleviation of opioid-induced constipation (OIC), with a view to realizing better pain management and improving the QOL of patients troubled by OIC.

Amid changes in the healthcare environment including the promotion of community-based healthcare and an accompanying rise in the importance of in-home care, we released tamper-resistant *OxyContin* TR tablets designed to encourage proper use of prescription narcotics in Japan, and prevent their misuse and abuse.

Going forward, we will continue striving to develop and market products that provide appropriate relief for cancer pain, addressing both the needs of patients and medical professionals, and changes in the social climate.

Measures to encourage proper use of pain relievers

Shionogi seeks to create a society in which patients suffering from cancer pain are able to use prescription narcotics with peace of mind. Recently the problem of prescription drug abuse, notably the opioid crisis in the US, has spread throughout the world, becoming a serious social problem.

To ensure that this problem does not arise in Japan, not only are we working to expand our lineup of drugs to alleviate cancer pain, but also we are taking steps in advance against misuse of opioids. In addition to helping create a society in which patients can get relief from cancer pain without causing abuse of opioids, we will work toward realization of Target 3.5 in the United Nations' Sustainable development goals (SDGs), "Strengthen the prevention and treatment of substance abuse, including narcotic drug abuse and harmful use of alcohol."

Drug abuse prevention campaign with Aichi Prefecture

May 2018: Shionogi is collaborating with Aichi Prefecture on a campaign to prevent drug abuse. To ensure that this problem does not arise in Japan, Shionogi pledges to do more to help create a society in which steps are taken in advance to prevent misuse of opioids, so that patients can get relief from cancer pain without causing abuse of opioids.

From left, Shionogi President and CEO, Isao Teshirogi, and Hideaki Ohmura, Governor of Aichi Prefecture

Dina Mired, UICC President Princess Dina Mired of Jordan pays a courtesy call on Shionogi

November 2018: Princess Dina Mired of Jordan, who serves as President of the Union for International Cancer Control (UICC), paid a courtesy call on Shionogi. We are focusing efforts on the treatment of cancer pain, and we were commended by Princess Dina for our support in helping to alleviate the pain of cancer patients by promoting the proper use of opioids and increasing access to such drugs.

From left, Princess Dina and Shionogi President and CEO, Isao Teshirogi

Combatting psychological and CNS disorders

Expanding treatment options for ADHD

ADHD is a neurodevelopment disorder characterized by three main symptoms—inattentiveness, hyperactivity, and impulsivity—and is a brain function impairment treatable by psychosocial therapy/support and medication.

Shionogi has been developing *Intuniv* and *Vyvanse* as treatments for ADHD, under a 2011 licensing agreement with Shire plc. (now Takeda Pharmaceutical) concerning joint development and commercialization in Japan.

Intuniv is a selective α2A adrenergic receptor agonist, the novel mechanism of action for the treatment of ADHD, and is a non-stimulant administered once daily. Launched in May 2017, *Intuniv* is now widely used in Japan. Furthermore, in June 2019 *Intuniv* won approval for the additional indication of treatment for ADHD in adults (aged 18 and over).

Vyvanse is a once-daily drug that stimulates the release of dopamine and noradrenaline, and blocks their reuptake. It is a prodrug that is therapeutically inactive until it undergoes gradual conversion to an active pharmacologic agent in the body, thus preventing a rapid rise in the active agent's serum level while ensuring that a steady serum level is maintained thereafter. Shionogi received manufacturing and marketing approval for *Vyvanse* in March 2019. Because *Vyvanse* is designated as raw material for stimulant, it was approved for marketing on the condition that certain measures be taken—that it should be given only to appropriate patients under prescription by medical experts well-versed in diagnosis/treatment of ADHD, and that it should be handled only by medical institutions and pharmacies, where risks including dependence can be fully controlled.

Shionogi seeks to contribute to treatment of ADHD patients by providing *Intuniv* and *Vyvanse* as new treatment options.

Support environment for more vigorous society

Support for children's bright future

Japan now leads the world in terms of its declining birthdate and graying population. Shionogi intends to build a sustainable society by creating an environment in which the children who will become our future leaders are able to maximize their potential and lead fulfilling lives.

The Office for Children's Bright Future at Shionogi seeks to lighten the psychological burden on children with a developmental disorder, with a twin focus on gaining greater understanding from society, and building and realizing a support system. As a partner in the support of children with a developmental disorder, we work together with local governments and academia, with an eye to harnessing the core competencies of all involved.

Partnering with local governments

In order to achieve earlier detection and intervention and realize lifelong support, Shionogi works in tandem with local governments to identify challenges particular to each region, and implement the necessary countermeasures.

Promoting understanding

Public seminars designed to promote wider and greater understanding of a developmental disorder
(Osaka, Hiroshima, and Iwate prefectures)

Improving the knowledge and practical skills of support staff

Workshops to enhance knowledge and practical skills among the various professions supporting children with a developmental disorder
(Osaka Prefecture, Hiroshima Prefecture, Sanuki City and Higashikagawa City in Kagawa Prefecture, Iwate Prefecture, and Yokohama City)

Training event for nursery and kindergarten teachers

Partnering with academia

With a view to building and realizing a support system for children with a developmental disorder, Shionogi is working alongside academic institutions to develop and promote useful new tools and methodologies.

Development of new tools

Development of tools to gauge the support needs and challenges faced by children with a developmental disorder, based on observation of such children at school
(Universities: Education field)

Promote training of support staff

Creation of training packages for special needs education coordinators at dedicated special needs schools and at elementary, middle, and high schools with a focus on special needs education
(Osaka Ohtani University: Faculty of Education)

Improving the knowledge and practical skills of support staff

Creation of guidebooks to support occupational health staff in assisting workers with adult ADHD symptoms
(University of Occupational and Environmental Health, Japan: Institute of Industrial Ecological Sciences' Occupational Health Practice and Management Department)

Shionogi has participated in a number of collaborative initiatives, and in May 2018 we entered into a new business alliance with Iwate Prefecture. In Hiroshima Prefecture, with which we had earlier formed a partnership in March 2018, we received recognition as a company conducting leading initiatives that can serve as a model for supporting people with disabilities.

Through this proactive approach, we aim to promote the growth and health of children who will become future leaders. We also seek to lighten the psychological burden on such children in order to help build a society in which individuals can tap their innate potential and thrive.

March 2018: Partnership with Hiroshima Prefectural Government to support our children's bright future
From left, Hidehiko Yuzaki, Governor of Hiroshima Prefecture, and Isao Teshirogi, Shionogi President and CEO

Initiatives to remove communication barriers for sight- and hearing-impaired people

Communication Barrier-free Project (CBF-PJ)
Ensuring that all patients have access to necessary information to receive benefits of best possible medicines

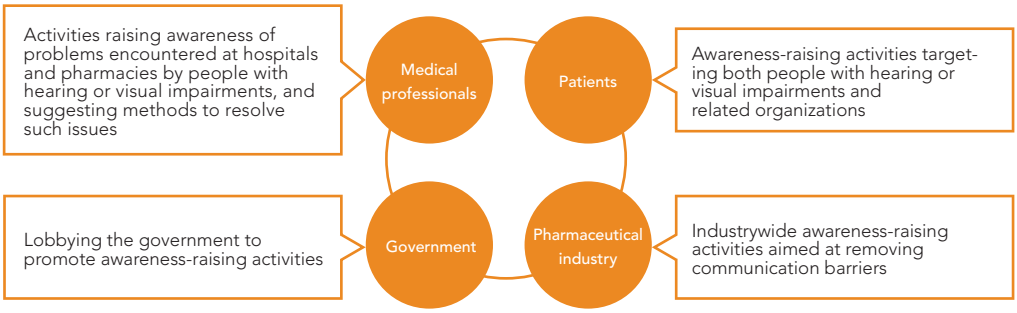
CBF コミュニケーションバリアフリー
気づきをカタチに、マイナスをプラスに

Pharmaceutical products have a direct impact on human health and life, and as such patients are provided with information—for example, through medication guidance from medical professionals—to ensure that drugs have maximum efficacy and minimal side effects.

At Shionogi, we think it extremely important that all patients—whether able-bodied or disabled—have access to the information necessary for medications to work properly. To that end, Shionogi has instigated the Communication Barrier-free Project, which seeks to improve the manner in which information is conveyed and eliminate communication barriers when people with disabilities receive medication instructions.

People with disabilities—in particular those with hearing or visual impairments—sometimes do not take medications as prescribed if they have not received sufficient information. While people with disabilities may struggle to take in information, this problem also can stem from the manner in which information is conveyed. Shionogi conducts activities aimed at educating various parties about the existence of such communication barriers. In 2018, we held a number of awareness-raising seminars targeting medical professionals, attended by 712 doctors, nurses, pharmacists, and so forth, from ten university and public hospitals.

Our aim is to contribute to creating a more vigorous society by ensuring that every individual—able-bodied or otherwise—receives the best possible medicines to protect their health and wellbeing, and is able to take these medicines in the appropriate manner.




Disability awareness seminar targeted at medical professionals


Booth exhibit at external event held by an interested party (All Japan Association of Hard of Hearing and Late-Deafened People)

The awareness-raising activities carried out under the banner of this project not only have contributed to greater understanding, but also have led to changes in behavior on the part of medical institutions.

Example: Addition of new "Ear mark" card*1 varieties

There are varying degrees of hearing impairment, and as such the type of consideration paid to patients also needs to vary. The university hospitals that hosted our seminars have since taken steps to better meet the needs of hearing-impaired individuals by adding new "Ear mark" card varieties and taking greater care when communicating with such patients.

Cards already available		Newly added cards
• "Please write it down" • "Please speak in a loud voice"	+	• "Please take off your mask" • Cards enabling patients to outline specific concerns

*1 "Ear mark" cards: Cards for presentation to hospital staff, signaling that a person is hard of hearing, and indicating the need to pay special consideration when communicating with a person who is hearing-impaired.

Create new value in the healthcare field

The current approach to social security provision is under question amid increasingly stretched healthcare budgets in advanced markets. Meanwhile, AI and ICT have opened the door to new ways of doing business in the pharmaceutical sector that were not possible in the past. Those trends mean we can no longer rely on our existing business model based solely on selling pharmaceutical drugs.

We seek to continue contributing to patients' treatment and QOL through our strength in the creation of innovative drugs, while also drawing on our expertise, skills, and experience in R&D to explore the possibilities of therapeutic and preventive vaccines, digital treatment option such as healthcare apps, and information services. By doing so, we aim to identify and address the issues that people face in all areas of healthcare, from pre-symptomatic and preventive care through diagnosis and treatment.

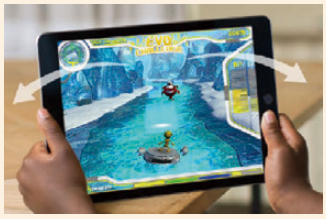
Investigational digital therapeutic, AKL-T01 (SDT-001)

AKL-T01 (Shionogi Group development code: SDT-001) is an investigational digital therapeutic for ADHD in-licensed from US-based Akili Interactive. Shionogi has acquired the development and commercialization rights for this product in Japan and Taiwan. In clinical trials conducted by Akili in the US, AKL-T01 showed a good therapeutic effect. Shionogi seeks to address the needs of ADHD patients by providing a new digital treatment option with SDT-001, along with the proprietary drugs *Intuniv*, which is currently on the market in Japan, and *Vyvanse*, which won approval in Japan in fiscal 2018.

SDT-001 operation screen

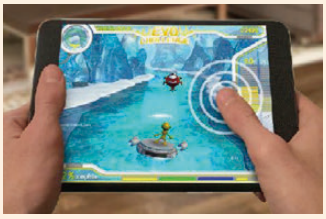
Stimulating the cerebral cortex by simultaneously performing dual tasks (steering and tapping) optimized for each patient

Steering



Steering: Avoid obstacles

Tapping



Tapping: React to specific objects

Initiatives of Shionogi Healthcare

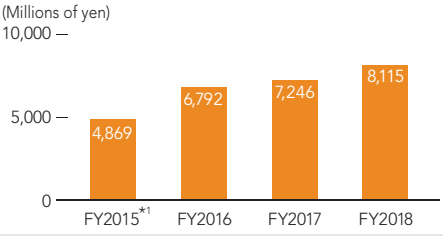
Against the backdrop of a shrinking birthrate and aging population, the role of self-care has expanded to include not just treatment, but also preventive and pre-symptomatic care, in order to extend healthy life expectancy.

Since its establishment in April 2016, Shionogi Healthcare has registered three consecutive years of growth by responding flexibly to changes in the operating environment. Going forward, Shionogi Healthcare remains committed on a daily basis to delivering new health value to patients through the provision of excellent products and service and appropriate information.

Products launched in fiscal 2018

2018	July	*Popon ai*
	August	*Isodine Clear* gargle Apple/Mint
		Pylon PL granules (24)
		Cinal EX chewable tablets e
		Cinal EX granules e
2019	March	*Kenkotsu Keikaku*
		Cinal L white EXIA

Net sales



*1. Sales in fiscal 2015 are those of Shionogi Pharmaceutical's Consumer Health Care Business Division; those for fiscal 2016 onward are for Shionogi Healthcare

Responding to societal changes arising from social security system reforms

In light of the pressure on public finances due to rising healthcare expenditures, consumers are being called upon to take responsibility for their own health, and practice self-care. In 2017, Shionogi launched *Pylon* PL granules as a cold medicine. The product was very well received by consumers, leading to the 2018 release of a larger packet. By supporting self-medication in this manner, Shionogi aspires to further improve consumers' QOL.

Addressing the evolving needs of the self-care market

June 2018: Capital alliance with Rohto Pharmaceutical

Shionogi formed a collaborative relationship with Rohto Pharmaceutical, with a view to meeting the diversifying needs of consumers looking to extend healthy life expectancy. The aim is to draw on the respective strengths of each company in working to improve QOL for as many people as possible.

Capturing the needs of a super-aging society

シオノギヘルスケア
シオノギ健康通販

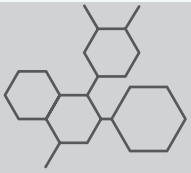
January 2019: Launch of Shionogi Health Mail-order Service, offering mail order sales of functional foods

In order to strengthen our presence in support for the pre-frail and promote the long-term health of seniors, Shionogi took over the Takara Group's functional food business, commencing direct sales of health foods.

As a company seeking to support consumer health, Shionogi will focus not just on pharmaceuticals for the treatment of illness, but also on developing foods contributing to preventive and pre-symptomatic care, and on the supply of information.

Material Issues to Realize a Sustainable Society and Support Shionogi's Growth

Shionogi aims to "grow sustainably as a drug discovery-based pharmaceutical company contributing to a more vigorous society through improved healthcare." To do this, we need to devote energy to achieving constant innovation and at the same time fulfill its duty as a public entity by taking account of social needs. By building a solid business foundation able to respond flexibly to changes in the environment, we are taking action to position Shionogi as a company whose future continuation is important to all stakeholders. In this section, we present the Group's specific initiatives and results in the area of material issues to realize a sustainable society and support Shionogi's growth.

Shionogi's Material Issues (Materiality)			page
	Drive innovation	Create new medicines that take into account economic efficiency in healthcare	P20
		Actively use diverse partnerships	P28
	Protect people worldwide from the threat of infectious diseases	Address the problem of antimicrobial resistance (AMR)	P30
		Tackle the world's three major infectious diseases	P34
		Promote proper use of anti-infectives	P35
	Creating a more vigorous society	Help end suffering from pain	P36
		Tackle psychological and CNS disorders	P37
		Support environments for more creative and vigorous lives	P38
		Create new value in the healthcare field	P40
S Social activities	Improve access to healthcare	Initiatives to improve access to healthcare	P44
	Supply socially responsible products and services	Ensuring quality and safety in products and services	P46
		Measures to stop counterfeit medicines	P49
	Secure human resources to support growth	Cultivating human resources to underpin competitiveness	P50
		Promoting diversity and inclusion	P52
		Protecting the health and safety of employees	P54
	Respect human rights	Respecting human rights	P55
		Ensuring the safety of participants in clinical trials	P55
	Reinforce supply chain management	Promoting CSR procurement	P56
E Environmental activities	Protect the environment	Responding to climate change	P58
		Protecting water resources	P58
		Saving resources and reducing waste	P59
		Appropriately managing chemical substances	P59
		Initiatives to protect biodiversity	P59
G Governance activities	Strengthen corporate governance	Establishing suitable corporate governance structures	P60
		Stakeholder engagement	P70
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	Ensure compliance	Strict compliance	P74
		Ensuring high ethical standards and transparency in business activities	P75

Improve access to healthcare

Shionogi believes that its basic stance should be as stated in the Company Policy: "to strive constantly to supply the best possible medicine to protect the health and wellbeing of the patients we serve." With this stance established as the basis of our value to society, we have progressed to our present position with our sights firmly set on the basic mission of a pharmaceutical company: to protect the health and wellbeing of the people we serve. Access to healthcare is a serious issue for many people around the world, and Shionogi is committed as part of its social responsibility as a pharmaceutical company to continuing the pursuit of this Company Policy through earnest initiatives to improve healthcare access.

Initiatives to improve access to healthcare

With a view to improving access to healthcare, we issued the Shionogi Global Health Access Policy Statement, which sets out our commitment to fulfilling our corporate mission by working, not only through our own efforts but also with a wide range of partners, to contribute to better health for people around the world, especially in developing countries. Specifically, we are progressing with the initiatives outlined below.

1) Since its foundation in 2013, we have been a continuous participant in the GHIT Fund, Japan's first private-public partnership of its kind, through which we are working proactively to overcome infectious diseases.
2) To improve access to healthcare, it is important to communicate medical knowledge accurately, improve disease awareness and rates of diagnosis among patients, and promote the proper use of medicines. To support the proper use of anti-infectives, we participated in the Industry Roadmap for Progress on Combating Antimicrobial Resistance, which aims to fight antimicrobial resistance by implementing the Davos Declaration of January 2016.
3) Since the patent for the anti-HIV agent dolutegravir, which is licensed to ViiV Healthcare, is available free of charge, generic manufacturers can manufacture low-priced generic versions and distribute them to more than 130 low-income and lower middle-income countries.
4) To reduce infant, child, and maternal mortality rates in Narok County, Kenya, we are collaborating with the international NGO World Vision to support improved access to healthcare services and improved nutrition through the Mother to Mother SHIONOGI Project.

Shionogi's initiatives for access to healthcare have received external recognition. With specific reference to its AMR initiatives, Shionogi was the only Japanese pharmaceutical company to qualify for inclusion in the Antimicrobial Resistance Benchmark 2018 survey, and was also recognized in the survey as having the highest annual ratio of R&D investment for anti-infectives of any of the companies surveyed (based on investment as a proportion of net sales).

Please refer to page 35 for details of the GHIT Fund and proper use of anti-infectives; pages 30–33 for details of AMR initiatives.

Detailed information on the Shionogi Global Health Access Policy Statement
http://www.shionogi.co.jp/en/company/policy/access.html

Intellectual Property and Access to Healthcare

Intellectual property is an extremely important business asset for pharmaceutical companies. Under Shionogi's intellectual property strategy, we protect various innovations, such as drug compounds, applications, crystalline forms, manufacturing methods, formulations, drug discovery targets and basic research technologies. As part of drug in-licensing and out-licensing activities, we conduct due diligence with respect to intellectual property and take every possible step to prevent Shionogi's business activities from infringing a third party's intellectual property. We also carry out brand design activities aimed at building trust in the Shionogi brand and preventing counterfeiting. Shionogi works to protect its intellectual property, employing all legal means necessary if Shionogi's intellectual property appears to have been infringed.

Shionogi does not consider that the system of intellectual property rights is in itself a barrier to drug access, but we are aware that in certain situations a degree of flexibility is required. In view of this, until the issue of drug access is resolved, we will refrain from applying for and enforcing patents in developing countries facing economic challenges that are classified as LDCs*1 or LICs*2.

Meanwhile, developing countries account for more than 40% of the total global supply volume of the anti-HIV agent *Tivicay* (dolutegravir), which is licensed to ViiV Healthcare, and its combination drugs *Triumeq* and *Juluca*. Registering dolutegravir in the Medicines Patent Pool has allowed generic manufacturers to manufacture dolutegravir, either as a single-ingredient formulation or combined with other anti-HIV agents, and distribute it to more than 130 low-income and lower middle-income countries. As one of the patent holders of dolutegravir, Shionogi contributes to this initiative.

*1 LDCs: Least Developed Countries
*2 LICs: Low Income Countries

Improving access to healthcare in Africa: Mother to Mother SHIONOGI Project

One project through which Shionogi seeks to serve the health of people worldwide is an initiative operated since 2015 in partnership with the international NGO World Vision. The aim is to reduce mortality among pregnant women and new mothers and babies in the Osupuko district of Narok County, Kenya.

Kenya has very few clinics for its large land area, which means that it is very difficult to arrange for pregnant women to receive the antenatal care that would ensure mother and child can return home in good health after the birth — a perfectly normal expectation in Japan. To tackle the high mortality rate for pregnant women and children up to 5 years of age along with other issues affecting mothers and their young children, we are engaged in building clinics and providing healthcare services to remote regions through traveling clinics and other projects. We are also working to improve access to healthcare by providing education on healthy living, nutrition, hygiene and related matters to healthcare professionals, local health workers, and community members.

The expansion of facilities through building of clinics, obstetrics wards, and other facilities has meant that, compared to before the start of the project, the number of pregnant women receiving antenatal examinations (4 times or more) has increased by 40-fold (from 5 before the project to 198 in its third year), the number of births at related clinics by 3.5-fold (from 6 before the project to 21 in its third year), and the number of children under five years receiving preventive vaccination by 23-fold (from 13 before the project to 305 in its third year). These figures reflect a progressive improvement in local health conditions.

With the project now in its fourth year, local awareness and behavior has begun to change as people appreciate the importance of giving birth at a medical facility and of receiving healthcare services at a clinic. Toward achieving Universal Health Coverage (UHC), we will continue supporting good health practice for mothers and babies worldwide to contribute to the health of people around the world.

A baby born at a health center with its mother

Hygiene education in action: mothers learn how to purify water

Participation in Access Accelerated*1

Shionogi has participated in Access Accelerated since 2017.

The Mother to Mother SHIONOGI Project is an initiative to improve access to healthcare for mothers and babies by enhancing local health services. As an Access Accelerated program, it was featured in the Access Accelerated Year Two Report. We will continue to promote initiatives through Access Accelerated to contribute to reaching one of the health targets of SDG 3: to reduce premature deaths from non-communicable diseases by one-third by the year 2030 through prevention and treatment and to promote mental health and well-being.

*1 Access Accelerated: an initiative that brings together more than 20 pharmaceutical companies from Japan, the US, and Europe to work with the World Bank, the Union for International Cancer Control (UICC), governments and other bodies to improve access to non-communicable disease (NCD) prevention, treatment and care in low- and lower middle-income countries.

ACCESS ACCELERATED *Moving NCD Care Forward*

Supply socially responsible products and services

In the more than 140 years since its foundation, Shionogi has never been responsible for a case of pharmaceutical damage to health. In keeping with the Company Policy of "striving constantly to supply the best possible medicine to protect the health and wellbeing of the patients we serve," our commitment to never allowing errors to occur has been passed down undiluted throughout our history. Accordingly, we strive to ensure quality and safety so that customers know they can rely on Shionogi medicines.

Ensuring quality and safety in products and services

Our approach to manufacturing: high-quality drugs in stable supply at competitive cost

To put into practice the Company Policy, we take Safety, Quality, Delivery, Low Cost, and Environmental Consciousness as the basis of our manufacturing activities. Going forward, we will continue to maintain an awareness of these five principles as we pursue earnest initiatives to realize a stable supply of high-quality drugs at reduced cost.

Initiatives to improve manufacturing quality

To consistently deliver a stable supply of high-quality drugs, Shionogi has put in place a quality assurance system based on Japanese and overseas GMP*1, allowing us to pass the inspections of regulatory authorities in the US and Europe. Each drug product must undergo an individual inspection for compliance with GMP. Shionogi obtains a GMP compliance certificate for all products before initiating drug manufacturing at our facilities.

At our manufacturing facilities, each lot is subject to tests and inspections to monitor product quality at every stage from receipt of raw materials through to the finished product. We also perform quality trend assessment and stability monitoring in an effort to realize continuous quality improvement. All data relating to drug manufacturing and quality are subject to appropriate document management to ensure the completeness of data as part of a system to consistently deliver the best possible medicines.

*1 GMP: Good Manufacturing Practice (regulations for pharmaceutical manufacturing control and quality control)

Initiatives for stable supply

Shionogi undertakes analysis of procurement risk for each product and responds through multisourcing and designation of safe inventory levels. By implementing this management cycle, we work to strengthen our system of stable supply. At the three Shionogi plants, we have put in place risk management and business continuity management systems to prepare for the event of suspension of operations through earthquake, fire, explosion, new strains of influenza, terrorist attacks or other major disasters and to facilitate rapid recovery and continuity. In this way, we work to ensure a system that will allow us to fulfill our responsibility to provide a stable market supply in all eventualities.

We maintain regular communication with significant contract manufacturers and suppliers in Japan and overseas to ensure that they share the Shionogi approach to stable supply and to set key performance indicators as common reference points to promote mutual understanding and strengthen coordination.

We support the Principles set out in PSCI*2 (whose code of conduct we require business partners to comply with) and, by complying with Japanese subcontracting law and other relevant regulations, we ensure that procurement activity is founded on honesty, fairness, equity, and transparency. At the same time, we work for sustained increase in corporate value so as to win still greater trust from our stakeholders.

*2 PSCI: Pharmaceutical Supply Chain Initiative (a non-profit body formed by more than 40 pharmaceutical companies worldwide to promote CSR-based procurement in the pharmaceutical industry)

Please refer to page 72 for details of our risk management and business continuity management systems; page 56 for details of PSCI.

Detailed information on the PSCI Principles (a code of conduct we require our business partners to comply with)
https://pscinitiative.org/resource?resource=1

Establishment of Shionogi Pharma

The new company Shionogi Pharma Co., Ltd., was established on October 1, 2018, to integrate the manufacturing-related functions of the Shionogi Group and began operations on April 1, 2019. In addition to pharmaceutical manufacturing functions, Shionogi Pharma is equipped with manufacturing and sales capabilities with functions in quality assurance and in supply chain, sales, and operations management. It thus has potential to develop a contracting business not only in drug manufacturing but also in investigational drug studies, analytical testing, pharmaceutical engineering, and other areas.

Through strengthening of manufacturing-related functions, we aim to move swiftly ahead with measures to ensure stable supply at reduced cost, maximize the value of long-listed drugs, and expand our contracting business. In this way we will not only advance Shionogi's business strategy, but also contribute to maintaining and improving the health of people around the world.

Technology development and manufacturing bases

- **Settsu Plant (Head Office):** main plant handling formulation and packaging for global distribution
- **Kanegasaki Plant:** integrated manufacturing base specializing in antibiotics
- **Tokushima Plant:** manufacturing plant for general APIs, intermediates, and highly potent APIs
- **Amagasaki Office:** R&D (manufacturing technology development), manufacturing base for investigational drugs

One-stop contract manufacturing system — offering solutions to customer issues

Shionogi Pharma's strengths lie in the following three points:

1. As a CDMO*1, Shionogi Pharma is equipped with all relevant functions from preparation of, formulation, and packaging to analysis and pharmaceutical engineering. It is thus able to provide a one-stop contract manufacturing system covering all stages from drug development to commercial manufacturing.
2. Technological prowess built up over a long history
3. Experience and trust based on a record of stable supply of high-quality drugs

*1 CDMO: Contract Development and Manufacturing Organization

On the basis of these strengths, Shionogi Pharma aims to provide services that meet customer needs and to contribute to the further development of the pharmaceutical industry. Shionogi aspires further to become a technology development-focused manufacturing company with emphasis on manufacturing technology, developing new manufacturing methods and products for global application. Shionogi Pharma operated booths at the CPhI Japan exhibition in March 2019 and at Interphex Japan in February and July 2019. There, we engaged in dialog with customers from Japan and overseas to analyze what issues customers face as a first step toward building a contract operations business.

A socially responsible system of quality management

The mission of the Corporate Quality Management Division is to ensure compliance with all regulations in operations relating to quality, safety, and pharmaceutical regulatory affairs, and to thereby ensure the reliability of these activities across the whole Group. This means that it coordinates closely with Group companies worldwide in the US, Europe, Asia, and other regions, working to improve the quality of Shionogi products and information, ensure safety through a robust pharmacovigilance system, and implement pharmaceutical compliance in the rapidly changing regulatory environment. In this way, it helps to fulfill Shionogi's responsibilities as a corporate citizen.

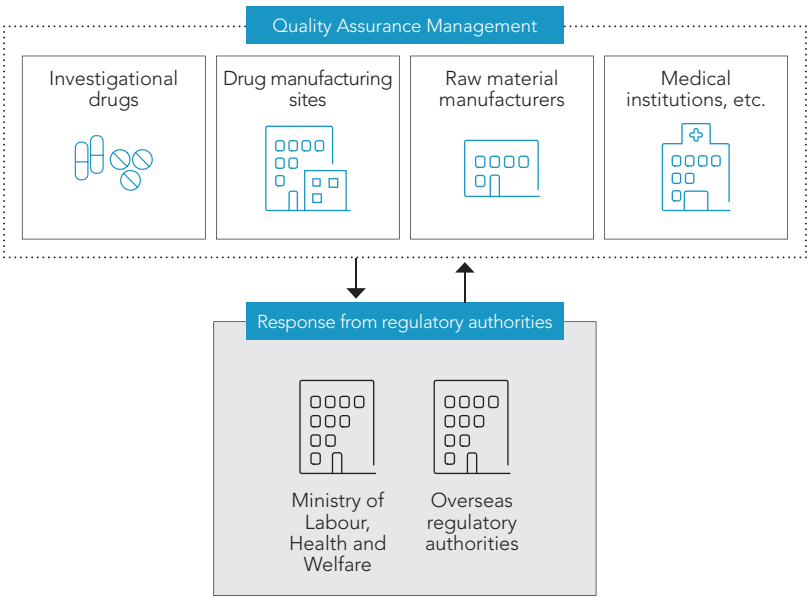
Going forward, we will continue to comply with regulations and take advance measures to avoid risk so as to make Shionogi a company that patients can have confidence in and all stakeholders can trust.

Action on quality assurance

To strive constantly to supply the best possible medicine to protect the health and wellbeing of the patients we serve, businesses must act efficiently with an approach to risk that takes preventive measures in advance rather than reacting after an issue has emerged. Among the quality risk scenarios envisaged, some are associated with the launch of new businesses and the establishment of new Group companies. Anticipating potential risk and devising mitigating measures makes it possible to respond appropriately and minimize the impact if and when the risk materializes. Through the Shionogi Group Quality Policy, which is subject to continuous improvement, Shionogi confirms that all products and data in Japan and overseas, from the development to the post-marketing stage, are covered by appropriate risk-preventive action of this kind.

Additionally, to implement these activities Group-wide, including in overseas operations, we put in place a quality assurance system compliant with the regulation of the relevant country. In addition to presenting a unitary policy, we also operate integrated information management, thus realizing a global quality assurance system for Shionogi products.

Detailed information on Shionogi Group Quality Policy
http://www.shionogi.co.jp/en/company/policy/quality.html



Building a pharmacovigilance system

Pharmacovigilance system

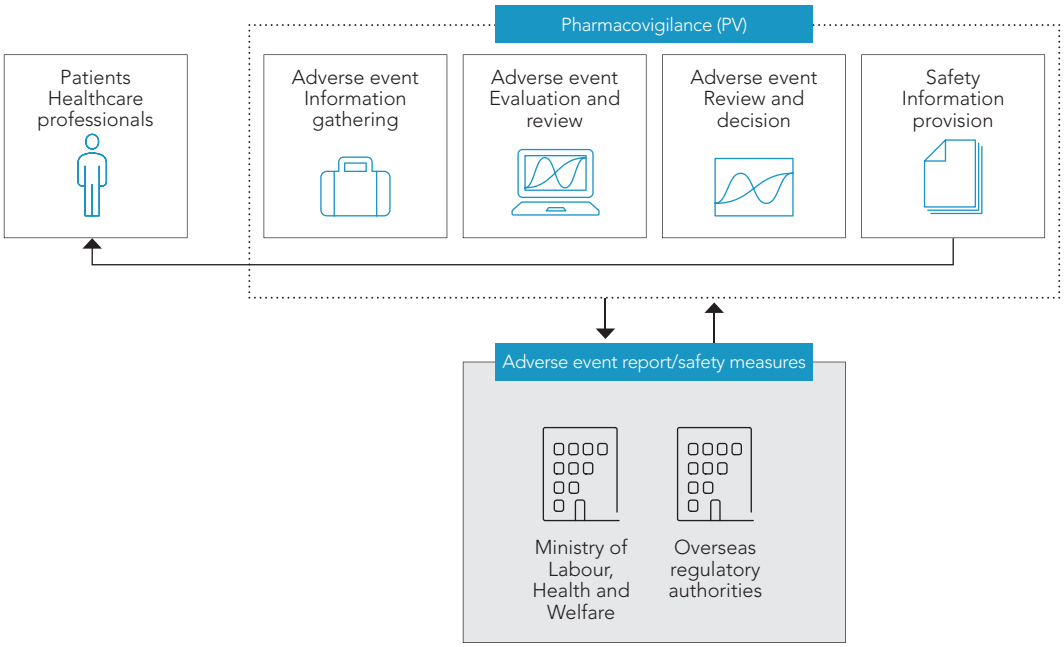
As set out in the Shionogi Group Drug Safety Policy, Shionogi gives utmost priority to the safety of patients and participants in clinical trials. Accordingly, we operate procedures for reliably gathering and evaluating safety information at all stages from development to post-marketing and have put in place a system which allows necessary safety measures to be rolled out rapidly through close coordination between safety management divisions in all Group regions, including overseas. Additionally, for drugs where it is considered necessary, a special pharmacovigilance system is put in place with specific procedures stipulated for the individual product. Through measures of this kind, we promote proper use tailored to the specific characteristics of the product.

Detailed information on the Shionogi Group Drug Safety Policy
http://www.shionogi.co.jp/en/company/policy/safety.html

Education for improved safety awareness

In order to ensure that safety measures are correctly implemented, it is vital that management and employees understand the importance of gathering and evaluating safety information. At Shionogi, in order to handle safety information appropriately, we formulate procedural manuals and provide in-house education. Within Japan, as well as regular training on gathering of safety information designed mainly for medical representatives (MR), we also provide safety education for general employees. In this way we work to improve awareness of safety in our business management.

Safety education: fiscal 2018 achievement record:
Safety control divisions 5 courses; Medical representatives 6 courses; Management 1 course; Company-wide education 1 course



Measures to stop counterfeit medicines

There is an increasing risk worldwide from counterfeit medicines, which not only represent a missed opportunity for patient treatment but may also result in health damage. Shionogi believes that, in addition to reliably delivering products to patients around the world living with disease, we also need to protect patients through initiatives to prevent the counterfeiting of medicines. To do this, Shionogi not only participates in industry activities to prevent the circulation of counterfeit medicines, but is also working under the lead of the Quality Assurance Department on a product security strategy through the Global Anti-Counterfeit Committee, whose members are drawn from various functions in Japan, the US, and Europe. Within Japan, in response to the case of a counterfeit version of a hepatitis C therapeutic drug that emerged in January 2017, a range of ministerial ordinances have been revised, resulting in a major review of in-house distribution management procedures and a comprehensive inspection of drug package seals and other areas. Going forward, we will carry on with continuous improvement of sealing, packaging and other areas, staying abreast of technological advances and of practice across the rest of the industry.

Secure human resources to support growth

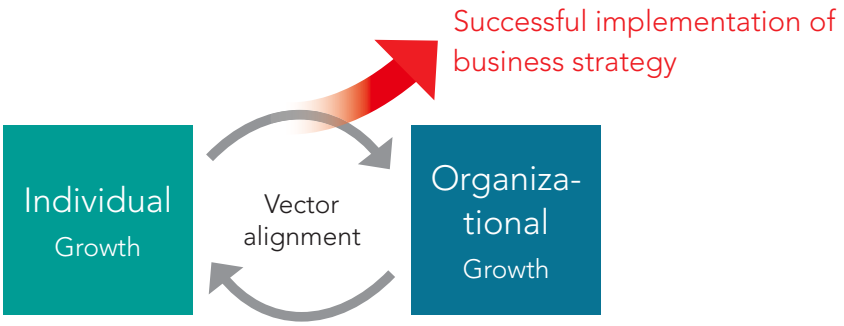
For Shionogi, creation of value depends wholly on its human resources. A diverse environment where people learn to respect and integrate different values and perspectives in a mutually motivating atmosphere can stimulate wide-ranging innovation. Leveraging this rich individuality as an energizing force, we provide our employees with opportunities to grow towards a future career path and provide them with a supportive work environment. This enables us to secure human resources who can drive sustained growth, leading both to personal growth and to growth of Shionogi as a company.

Cultivating human resources to underpin competitiveness

Career development at Shionogi

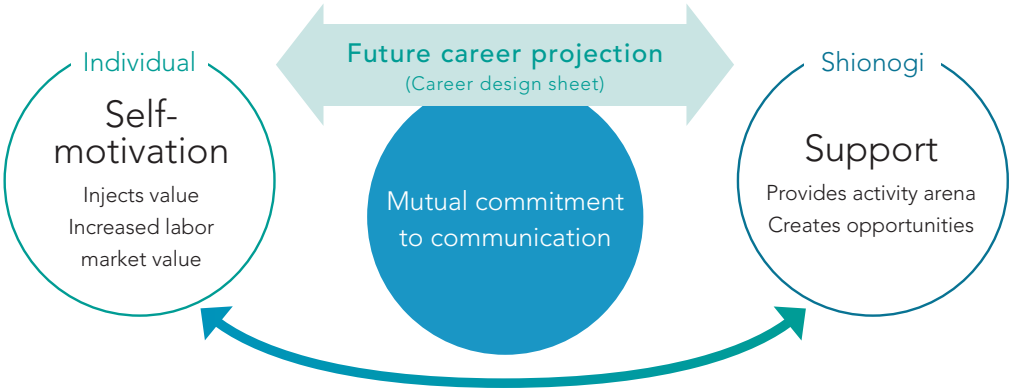
Approach

To put the Company Policy into practice globally, our aim is to succeed against global competition by cultivating strong individuals to build our organization based on the policy that people are the source of competitiveness for human resources development.



People experience motivation and work satisfaction when they have achieved growth in their career and been able to contribute to the wider organization. We focus on individual strengths and value the ability for self-realization in the workplace.

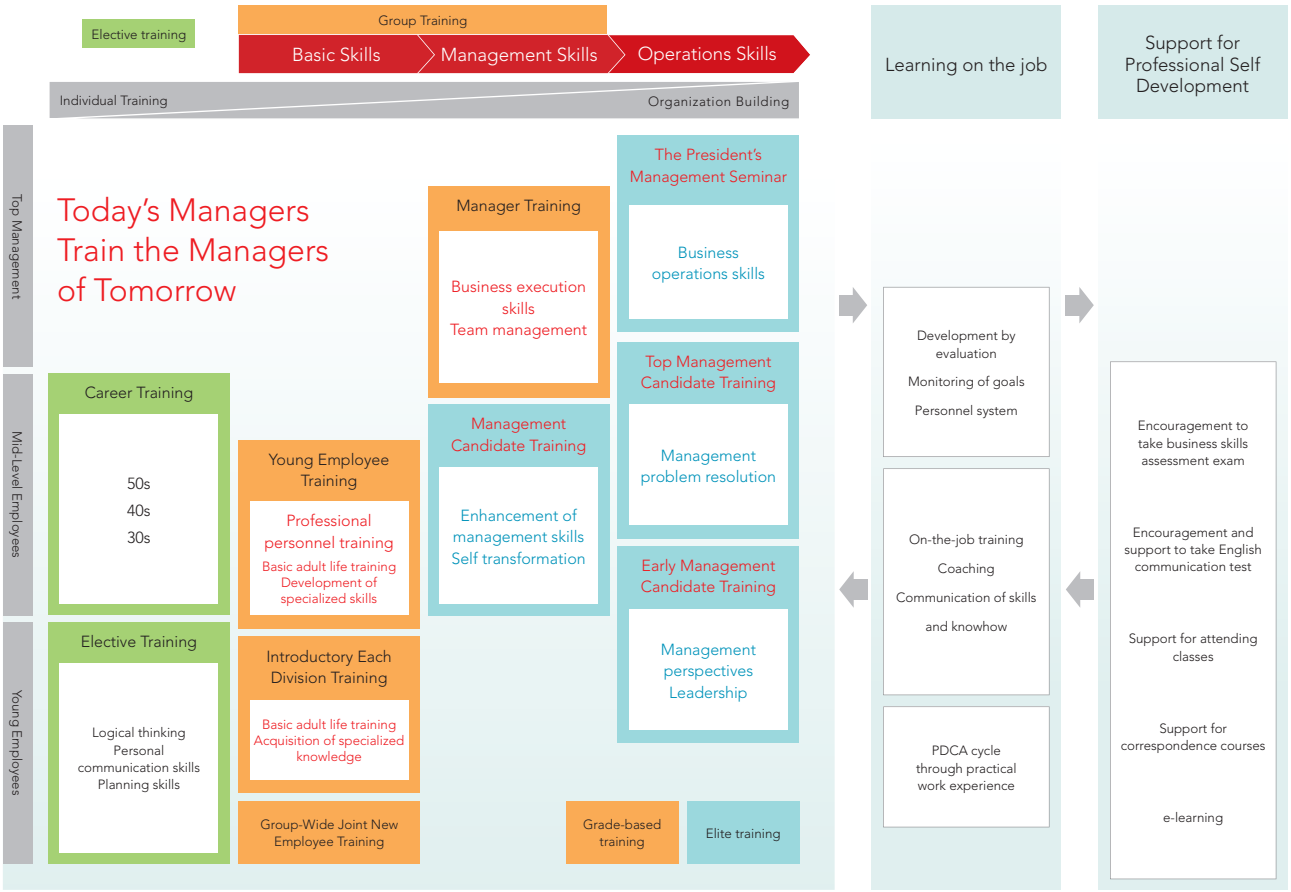
Within the context of everyday discussion and dialog, we encourage individuals to proactively seize opportunities by communicating their wishes to senior staff based on future career projections. In response, senior staff create an environment that supports growth by assigning projects to optimally match team members' strengths. In this way, we promote self-motivated human resources development oriented toward career growth.



Cultivating next-generation leaders

Employee growth is the essential driver of Shionogi's growth. To deliver new value to society, we establish an outline of the human resources profile and the managerial profile that the company requires, and managerial staff take corresponding responsibility for employee development. So that each individual employee can evolve toward continuous development in their thinking and their actions, we support all employees to take control of their own future growth.

Outline of Human Resources Development



The President's Management Seminar

The President's Management Seminar, which is led by the President in person, is a forum set up in 2012 to cultivate senior management candidates. Each year around ten candidates are selected to participate in a total of seven to nine seminars held roughly every month over the course of the year. In the seven years since its inception, the program has turned out over 50 graduates in all, including half of our current corporate officers and around 40% of heads of organization. Through this program, Shionogi cultivates its next generation of leaders by developing diverse human resources with a tenacious approach who can consider issues from a company-wide perspective.

Senior management development through management experience at Group companies

Senior management candidates take on roles as presidents, non-executive directors, and auditors of Group companies, where they gain management experience. The president of the Shionogi Group himself confirms the content of discussions at Group companies. At the twice yearly general meeting of shareholders and at business briefing events, the president of the Shionogi Group and officers of Group companies are engaged in comprehensive discussion, providing them with a forum to deepen their understanding of the stakeholder perspective and hone their business instincts.

Divisional rotation of corporate officers

Shionogi carries out a system of corporate officer rotation across divisions. This rotation allows corporate officers to experience management of a number of divisions so that they can practice management not as the representative of one division but from a company-wide perspective.

Promoting diversity and inclusion

Continuous innovation is vital to ensure that companies remain viable and continue fulfilling their responsibility to society. Shionogi emphasizes diversity and inclusion as a driving force of innovation. Learning to respect and integrate diverse values and perspectives within a mutually motivating atmosphere can stimulate wide-ranging innovation, which increases our ability to benefit patients and society and in turn strengthens Shionogi's business viability.
Guided by this approach, in 2018 we established a system to promote diversity and inclusion on a Group-wide basis by creating the Diversity Council, which coordinates the separate efforts of individual organizations to facilitate diversity and inclusion. A Diversity Vision was also created so that all employees can engage in promoting diversity and inclusion on the same level as each other.

Diversity Vision (Establishment in December 2018)

Understand yourself and others,
and celebrate individual diversity.
Allow the wide variety of unique qualities to
inspire creativity and innovation.

We will
have an unbiased understanding of others, knowing that everyone has a different perspective;
connect and resonate with diverse personalities to foster an inclusive spirit and generate abundant ideas;
and, driven by such spirit and ideas, create new value and grow with society for our collective future.

Creating a supportive workplace for people with disabilities

Shionogi is actively engaged in employing people with disabilities from the following perspective: progressing with the adaptation of workplaces so that people with and without disabilities can work vigorously.

Since 2014, we have been working to create supportive work environments in which people with disabilities can develop their abilities. To create further employment opportunities, in April 2018 we established Shionogi Smile Heart Co., Ltd., which was certified as a special subsidiary company in July 2018.

Aspiring to be an organization where barriers to communication are removed and all people can fully tap their innate potential and thrive irrespective of their disability status, we are rolling out an initiative known as the Project for Barrier-Free Communication. As the project applies equally to our own organization, we are working on ways of guaranteeing appropriate access to information so that anyone can participate in meetings independently. Using voice recognition apps to convert speech to text and inserting subtitles into video presentations are among the specific measures for employees with hearing impairment whose introduction is making it the norm for all employees to have guaranteed access to information. Meanwhile, as part of in-house training activities, we use simulations and other methods to give employees an understanding of the unique experience of hearing impairment.

Going forward, we will continue working to create an environment where people with disabilities who wish to work can join the Shionogi family, where they can pursue their career vigorously, their individual abilities are respected and their work duties and working environment are adapted to their particular disability.

Please refer to page 39 for details of external initiatives as part of the Project for Barrier-Free Communication.

Supporting work-life balance

To help our employees achieve an appropriate work-life balance, we have taken steps to offer more convenient work solutions by actively introducing a discretionary work system and a flextime system. Close to 100% of eligible female employees take childcare leave and return to work afterwards, while more than 20% of eligible male employees currently take childcare leave. We have also introduced a variety of options to support diverse employee lifestyles. These include a system that lets sales staff choose their work location to adjust to major life changes, such as getting married or taking on childcare responsibilities, a leave system for volunteering, a leave system for bone marrow donors, and a leave system to support learning.

Since 2005, we have been working to comply with Japanese legislation designed to create more supportive environments for child-rearing. This requires us to draft a series of employer action plans, whose content has included efforts to increase the uptake rate of annual paid leave, introduction of partial pay for childcare leave, and support for employee personal development during leave periods. We have also held relevant training seminars for managerial staff and have introduced a system of interviews to give guidance to employees about to start or complete a leave period. In recognition, we have three times received the Kurumin Mark, which is awarded by the Japanese Ministry of Labour, Health and Welfare to companies that support child-rearing.

Promoting the empowerment of women

At Shionogi, we are committed to providing employees with a work environment in which they can develop their strengths, express themselves as individuals, and develop professionally regardless of gender.

As a result of our initiatives to date, the ratio of female managers has been rising steadily and now stands at 10% in our domestic Group companies. With the male-female gap in average years of service also now closed (males 17.1 years, females 17.8 years), Shionogi is evolving into a company where it is considered only natural that women are active in the workplace.

In response to Japanese legislation for female empowerment, employers are required to publish relevant action plans. In fiscal 2019, as part of our plan for the period April 1, 2019 to March 31, 2021, we set the goal of having at least 10% of managerial positions occupied by women by the end of fiscal 2020. Among other initiatives in our continuing support for women's professional advancement, we plan to (1) conduct seminars and other educational activities on the subject of diversity company-wide (2) hold seminars on female career development for managerial staff (3) introduce a discretionary work system, a flextime system, and a homeworking system (4) look at measures to support employees returning to work from child-rearing leave, for instance provision of useful information during leave on a voluntary basis.

Awards for Diversity

New Diversity Management Selection 100
Shionogi has rolled out initiatives to support employee career development and to promote female advancement in the Human Health Care Division. The thinking behind these and other initiatives is that supporting diverse human resources to develop their strengths will not only lead to personal growth but will also contribute to the growth of the organization. These efforts were recognized when Shionogi was selected for inclusion in the fiscal 2015 New Diversity Management Selection 100 project.

Leading Company for Women's Advancement in Osaka City
As a company that takes active measures to create a supportive work environment for women, Shionogi was certified in fiscal 2015 as a leading company for women's advancement in Osaka City.

Kurumin Mark
Shionogi has three times been awarded the Japanese Minister of Labour, Health and Welfare's Kurumin Mark, which recognizes it as a company that supports child-rearing.

'Eruboshi' Grade 3 award and certification as an outstanding equal opportunities employer
Shionogi Techno Advance Research, a Shionogi domestic Group company where around half of employees are women, aims to realize a work environment where women can continue energetically pursuing their career while coping with life's milestones such as pregnancy, childbirth, child-rearing, and taking on career responsibilities. As part of these efforts — partly in response to a survey of workplace morale in fiscal 2016 — the company was inspired to set up a Women's Advancement Promotion WT, whose activities are led by employees. In December 2017, the company received Grade 3, the highest rating, in the 'Eruboshi' awards, which were set up under Japanese legislation for female empowerment. In May 2018, it was designated by Osaka Prefecture as an outstanding equal opportunities employer.

Protecting the health and safety of employees

Health management

Shionogi takes focused measures to provide an environment in which employees can approach their work vigorously and thereby maintain health. We believe that this not only increases employee productivity but also helps to secure high-quality human resources. Our basic approach to activities to maintain and improve health is set out in the Shionogi Health Declaration 2018, which guides our efforts to adapt and improve the work environment.

Selected as Health and Productivity Stock for Four Consecutive Years

In February 2019, Shionogi was selected as a Health and Productivity Stock and as one of the 'White 500' group of organizations certified for Outstanding Health and Productivity Management. Health and Productivity Stocks are stockmarket-listed enterprises selected in a program operated jointly by the Japanese Ministry of Economy, Trade and Industry and the Tokyo Stock Exchange to recognize companies that take a managerial perspective on employee health management and offer a strategic response. Shionogi's activities to maintain and improve health have received strong public recognition, indicated by our inclusion in the selection for the fourth successive year since 2016.

Detailed information on Shionogi Health Declaration 2018
http://www.shionogi.co.jp/en/company/csr/index.html

Occupational health and safety

We work to protect employee safety and health and create an optimal work environment by putting in place a relevant management system, operating a Health and Safety Committee, and taking other measures to prevent work-related accidents and ensure health and safety in the workplace.

The Settsu and Kanegasaki Plants have received certification under OHSAS 18001 (Occupational Health and Safety Management System Standards) and practice continuous improvement. Meanwhile, to create a safer operating environment by preventing accidents due to chemical substances, we have put in place a management system using safety data sheets and maintain optimal chemical hazard guidelines.

Please refer to our EHS Report for details of health management and occupational health and safety.
http://www.shionogi.co.jp/en/company/csr/activities/environment.html

Respect human rights

Shionogi, which has declared its wish to create a more vigorous society, recognizes the importance of respect for human rights and related initiatives. We believe that it is important for each employee to respect human rights and to act from a high ethical stance in accordance with international standards such as the Universal Declaration of Human Rights and the ILO's international labor standards. The Shionogi Charter of Conduct, which lays down standards for employee conduct, contains clear statements regarding Respect for the Individual and Acceptance of Diversity.
Since joining the PSCI*1 in 2017, Shionogi has been progressing with human rights initiatives embracing all of its corporate activities, including suppliers.

*1 PSCI: Pharmaceutical Supply Chain Initiative (a non-profit body formed by more than 40 pharmaceutical manufacturers worldwide to promote CSR-based procurement in the pharmaceutical industry)

Please refer to page 56 for detail of participation in PSCI.

Detailed information on Shionogi Charter of Conduct
http://www.shionogi.co.jp/en/company/business/guideline.html

Action on UN Global Compact

With business operations set to extend worldwide, Shionogi has the responsibilities of a global corporate citizen and needs to contribute to resolving social issues as part of its management activities. Accordingly, in August 2019 Shionogi declared its participation in the United Nations Global Compact.

In the interests of sustainable growth, Shionogi endorses the essential values expressed in the ten principles of the United Nations Global Compact relating to human rights, labor, the environment and anti-corruption. Going forward, Shionogi will continue to support and respect the protection of human rights, avoid complicity in human rights abuses, and promote still more energetically global-level initiatives to eliminate forced labor and child labor.

WE SUPPORT
UN GLOBAL COMPACT

The Ten Principles of the UN Global Compact

Human Rights	Principle 1: Businesses should support and respect the protection of internationally proclaimed human rights; and Principle 2: make sure that they are not complicit in human rights abuses.
Labour	Principle 3: Businesses should uphold the freedom of association and the effective recognition of the right to collective bargaining; Principle 4: the elimination of all forms of forced and compulsory labour; Principle 5: the effective abolition of child labour; and Principle 6: the elimination of discrimination in respect of employment and occupation.
Environment	Principle 7: Businesses should support a precautionary approach to environmental challenges; Principle 8: undertake initiatives to promote greater environmental responsibility; and Principle 9: encourage the development and diffusion of environmentally friendly technologies.
Anti-Corruption	Principle 10: Businesses should work against corruption in all its forms, including extortion and bribery.

Ensuring the safety of participants in clinical trials

Clinical trials carried out by Shionogi are conducted in compliance with the Helsinki Declaration, the ICHGCP and other guidelines, and Japan's Pharmaceutical Affairs Law or other regulations applicable in the country where the trial is conducted. In the case of participation in a clinical trial, written informed consent is obtained based on the free will of the participants and the utmost efforts are made to protect the participants' human rights, ensure their safety and improve their well-being.

Specifically, in all clinical trials that Shionogi carries out, the highest priority is shown for ethical concerns. To guarantee the appropriateness of the trial in scientific and medical terms, it is conducted in accordance with a trial protocol that has been reviewed and approved by independent review committees established within the Company and within the medical institution (ethics committee/institutional review board).
Additionally, during the conduct of the clinical trial, a staff member of the medical institution is responsible for collecting safety information on the participants, and where safety information relating to newly observed serious adverse events in the participants is received, a prompt report is made to the participating medical institutions and the regulatory authority of the relevant country in accordance with GCP, the regulatory provisions of the country, and company regulations. In this way, the utmost efforts are made to ensure the safety of participants in the clinical trial.

Reinforce supply chain management

To ensure that corporate social responsibility is fulfilled, as well as monitoring its own organization, Shionogi needs to build relationships of trust and cooperation with suppliers, who are important business partners. The Shionogi Group's Procurement Policy sets out a basic approach designed to ensure that procurement activity is founded on honesty, fairness, equity, and transparency, and forms the basis on which we work together with suppliers to strengthen supply chain management.

Promoting CSR procurement

Participation in PSCI

The PSCI Principles form a code of conduct which we require business partners to comply with. They cover a comprehensive range of fields including not only the environment and health and safety but also employment rights, ethical standards, and associated systems of management. Shionogi not only supports the PSCI Principles itself, but also requires its suppliers to abide by them.

PSCI Principles (Extracted items only)

[Ethics]
1. Business integrity and fair competition
2. Identification of concerns
3. Animal welfare
4. Privacy

[Environment]
1. Environmental authorizations
2. Waste and emissions
3. Spills and releases

[Health and Safety]
1. Worker protection
2. Process safety
3. Emergency preparedness and response
4. Hazard information

[Labor]
1. Freely chosen employment
2. Child labor and young workers
3. Non-discrimination
4. Fair treatment
5. Wages, benefits and working hours
6. Freedom of association

[Management systems]
1. Commitment and accountability
2. Legal and customer requirements
3. Risk management
4. Documentation
5. Training and competency
6. Continual improvement

PSCI PHARMACEUTICAL SUPPLY CHAIN INITIATIVE
Building responsible supply chains

Detailed information on PSCI Principles
https://pscinitiative.org/resource?resource=1

Audit activity

We require suppliers of important pharmaceutical raw materials to undergo an EHS*1 audit to check on safety measures in the manufacturing process and elsewhere and ensure environment-conscious operations. Our Suppliers' EHS/CSR Management Guidance sets out EHS risk categories and risk management procedures for suppliers and stipulates which conditions they must meet according to their assigned management level. We carry out a survey using the PSCI's self-assessment questionnaire to confirm the supplier's status in areas including ethics, labor, the environment, and health and safety.

In fiscal 2018, 24 suppliers consented to the code of conduct based on the PSCI Principles and underwent a questionnaire-based written audit. Subsequently, visits were made to nine of the suppliers to carry out on-site audits.

*1 EHS: Environment, Health and Safety

Protect the environment

At Shionogi, we have built up a company-wide management system based on the Shionogi Group EHS Policy, whose EHS activities embrace not only the Group but also its supplier partners.
Our medium-term business plan Shionogi Growth Strategy 2020 (SGS2020) is a growth strategy looking ahead to the year 2020 and sets out initiatives aimed at addressing social issues and increasing corporate value. We recognize environmental protection, which is also addressed in the United Nations' SDGs, as a key issue for companies to tackle in their operations. Accordingly, we have carried out an assessment of EHS-related business risks and environmental impacts and responded by setting the Shionogi Group EHS Action Targets, whose key point activities are outlined below.

1) Antimicrobial resistance (AMR): reduce environmental burden arising from antibiotic manufacturing
2) Climate change: assess climate change-related risks associated with CO_2 emissions and water resources and formulate response strategies
3) Recycling-based society: formulate strategy for resource recycling and waste treatment/disposal (water, plastics)

Please refer to pages 30–33 for details of our AMR initiatives.

Our EHS Report carries further information on EHS-related business risks and identified material issues and details of our EHS activities:
http://www.shionogi.co.jp/en/company/csr/activities/environment.html

Detailed information on Shionogi Group EHS Policy
http://www.shionogi.co.jp/en/company/policy/ehs.html

Medium-Term Business Plan SGS2020 → Identifying external and internal changes and challenges → Initiatives on Shionogi Group EHS Action Targets

To grow sustainably as a drug discovery-based pharmaceutical company contributing to a more vigorous society through improved healthcare

Growth Regions and Area

Focusing on Japan and the US
Strengthening bases in Europe and Asia

Infectious diseases
Pain / CNS disorders

+

Keys to Growth

Addressing society's needs

Balancing innovation and healthcare affordability

Identification of Shionogi Group's Material Issues (Materiality)

Material Issues to create new value for customers and society

Material Issues to realize a sustainable society and support Shionogi's growth

Changes in External Environment
- Global warming countermeasures (Paris Agreement)
- Adoption of SDGs
- Measures to combat antimicrobial resistance, etc.

Changes in Internal Environment
- Establishment of new Group companies
- Increase in EHS audits by customers
- Establishment of CSR Department and EHS Office, etc.

Sustainability of the global ecosystem

Designate key environmental issues

Business continuity and increase in corporate value

Use environmental risk management to assess risks and opportunities

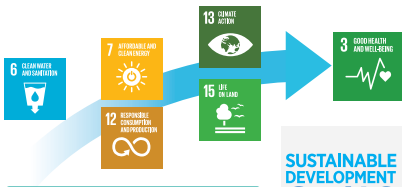
•AMR/Climate change/Water
•Plastics •Chemical substances •Biodiversity

Shionogi Group EHS Action Targets

1. Promote energy conservation and global warming control measures
2. Strengthen resource conservation and waste treatment/disposal measures
3. Manage chemical substances appropriately
4. Develop EHS management systems
5. Ensure a sound aquatic environment
6. Contribute to biodiversity preservation
7. Work toward zero occupational accidents resulting in lost work time
8. Introduce EHS initiatives to the supply chain
9. Promote health and productivity management

Contribute to solving EHS-related issues in the process of addressing SDG 3, "good health and wellbeing"

To grow sustainably as a drug discovery-based pharmaceutical company contributing to a more vigorous society through improved healthcare



Reduce CO_2 emissions
Reduce water consumption, etc.

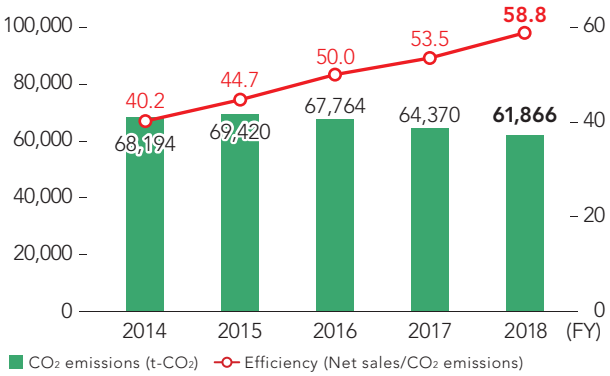
Responding to climate change

Shionogi recognizes global warming and other climate change issues as themes to be addressed by management and is progressing with measures to reduce CO_2 emissions. It is also taking action to identify climate change-related risks and opportunities. To do this, we have carried out assessments of their probability of occurrence and potential financial impact, adopting the definitions of the TCFD*1 and making reference to the IPCC Fifth Assessment Report*2 and the RCP 2.6 and 8.5 scenarios.

Shionogi is actively working on CO_2 emission reduction to contribute to global warming alleviation, and to that end has adopted the goal of reducing CO_2 emissions in fiscal 2020 by 33% from the fiscal 2005 benchmark. Since achieving a major CO_2 reduction in fiscal 2014 through fuel switch, we have continued to steadily decrease CO_2 emissions, for instance by introducing highly efficient facilities and reviewing operating methods. Our EHS Report discloses Group greenhouse gas emissions, including those of overseas operations, with the relevant greenhouse gas emissions (marked with a check) subject to third-party guarantee.

*1 TCFD: Task Force on Climate-related Financial Disclosures
*2 IPCC Fifth Assessment Report: a report by the IPCC (Intergovernmental Panel on Climate Change) which gives an overall assessment of climate change from scientific and socioeconomic perspectives.

CO_2 emissions



	Details	Financial impact	Probability	Remarks
Transition risk (strengthened regulation)	Additional investment costs for energy-saving measures	Medium (Capital investment)	Medium	Assuming strengthened regulation to align with science-based target (SBT) levels
Physical risk (extreme meteorological phenomena)	Interruption of operations through damage to company plants	High (Interruption of operations)	Low	Assuming damage to plants by irregular weather events on a level with torrential rains of July 2018
Physical risk (extreme meteorological phenomena)	Interruption of operations through damage to supply chain	High (Interruption of operations)	Low	Assuming supply chain risk from increased irregular weather events in Asian region
Opportunity (enhanced external recognition)	Increased investment from investors	Medium (Investment opportunity)	Medium	Assuming enhanced evaluation of ESG based on information disclosure in Integrated Report/EHS Report
Opportunity (CO_2 emissions reduction)	Reduction of electricity costs through further energy-saving measures	Medium (Reduced operating costs)	Medium	Assuming electricity consumption levels after SBT standards are reached
Opportunity (participation in new markets)	Increased income from climate change-related new drug creation	Medium (Income)	Low	Assuming change in tropical infectious disease market (malaria)

Protecting water resources

High-quality water is a resource essential to pharmaceutical manufacturing. Water shortage in the water catchment areas where our plants are located would have a major impact on business continuity. For each of the main business locations involved in Shionogi's manufacturing and research, we have therefore conducted an assessment of the water supply necessary for current and future business continuity and of water-related risks, including increased probability of flooding due to climate change-related extreme meteorological phenomena. These assessments were carried out using the international assessment tools WRI Aqueduct and WWF Water Risk Filter. As a result of an overall judgment based on these assessments, combined with past insights and experience, Shionogi has concluded that its current and future water-related risk is relatively low. Going forward, we will consider consultations with experts in the assessment of water-related risk.

By additionally integrating risk assessment based on WRI Aqueduct into the supplier selection process, we are working to identify and reduce potential supplier risk.

Shionogi is working to protect water resources by using them more effectively and managing wastewater quality. In addition to our efforts to conserve water, we set voluntary standards for wastewater quality that exceed mandated levels and carry out constant monitoring.

Initiatives on AMR

To reduce environmental burden at Shionogi antibiotics manufacturing sites, antibiotics contained in wastewater are subject to an inactivation process before being sent to an on-site wastewater treatment facility, where checks are made to ensure that any substances released into the natural environment are at a harmless level.

Saving resources and reducing waste Environmental strategy for plastics resources

The increasing world population and economic development have contributed to creating a society characterized by mass production, mass consumption, and mass disposal. This has given rise to environmental issues such as depletion of natural resources, destruction of the natural environment, and pressure on final waste disposal sites, with resulting calls to limit the consumption of natural resources and alleviate the environmental burden. Meanwhile, at the G20 summit held in Osaka in June 2019, participating nations agreed on a target of reducing marine plastic waste to zero by the year 2050. A strategy to deal with plastic resources is thus becoming an urgent priority.

Shionogi is itself a user and disposer of resources, for instance as pharmaceutical raw materials and in research materials and equipment. In accordance with the Shionogi Group EHS Policy, we are working to reduce the generation of waste and promote reuse and recycling, and at the same time working to reduce the environmental burden associated with the products we sell. In addition to changing the materials used in packaging and containers and saving material by downsizing, we are progressing with the switch to carbon-neutral biomass plastics and high-quality recycled plastics, whilst ensuring that product quality and stable supply are maintained.

Policy	Action	Products affected
Reduce	Change of tray material (from plastic to paper)	All ampoule, vial, and tube products
	Change of thickness of eye drop container (thinner)	All eye drop preparations
	Change of thickness of PTP packaging material (thinner)	*Flomox* tablets
	Elimination of plastic buffer material from bottle packaging	*Irbetan* tablets, etc.
Reuse Recycle	Labeling of plastic container packaging with identification mark	All products
	Switch to mechanically recyclable PET film	*Intuniv* tablets
Renewable	Switch to biomass bottles (made with plant-derived polyethylene)	*Cymbalta* capsules, *Irbetan* tablets, *Pirespa* tablets

Appropriately managing chemical substances

We use a wide range of chemical substances in pharmaceutical research, development, and manufacturing. Included among these are chemical substances with potential impacts on human health, ecosystems, and the global environment. For the sake of compliance, we believe that it is important not only to strictly observe PRTR legislation and the wide range of other regulations relating to chemical substances, but also to appropriately manage chemical substances and observe voluntary standards more stringent than legally mandated values in order to limit emissions into the air, wastewater, water, and soil.

Initiatives on AMR

Action in response to antimicrobial resistance (AMR) is a worldwide challenge. As an antibiotics manufacturer, Shionogi believes that action to suppress the emergence of resistant bacteria is vital and we are taking relevant action with the cooperation of suppliers. Shionogi has completed an audit of plants that manufacture antibiotics and all domestic suppliers. For details of the audit results, see our EHS Report.

Initiatives to protect biodiversity

To promote biodiversity-conscious environmental activity, we at Shionogi set Action Targets, undertake employee education, and take action in compliance with the Invasive Alien Species Act and the "Cartagena Act" (Act Concerning the Conservation and Sustainable Use of Biological Diversity through Regulations on the Use of Living Modified Organisms).

Supporting local community education through the Aburahi Botanical Gardens

Shionogi operates the Aburahi Botanical Gardens, which serves as a place for preserving rare plants, including endangered species, and for education on biodiversity

Students at Aburahi Elementary School enjoy dyeing workshops using plants grown in an herb garden built on the school grounds. They also learn about medicinal plants by touching and observing plant roots, leaves, seeds, and fruits in the Botanical Gardens. These classes are organized in partnership with Koka City Kusuri Gakushukan (Pharmacological Learning Center) and other local corporations, with experts from the botanical gardens of Kobe and Kyoto Pharmaceutical Universities serving as guest lecturers. The program has won strong recognition as an initiative that supports the education of the children who are our future through collaboration between local government, academia, and industry.

Workshop for elementary school students

Strengthening governance

Establishing suitable corporate governance structures

All the Company's directors are committed to practicing transparent and fair management while supporting sustained growth and increasing corporate value over the medium and long term.

Board of Directors

From left: Hiroshi Ozaki, Takuko Sawada, Motozo Shiono, Isao Teshirogi, Ph.D., Teppei Mogi, Keiichi Ando

Basic views on corporate governance

Shionogi has created a corporate governance structure to make its Company Policy a reality worldwide. The Group defines corporate governance as a structure for transparent, fair, timely and decisive decision-making that pays due attention to the needs and perspectives of shareholders, customers, employees, local communities and other stakeholders. Based on this, the Group formulated the Basic Views and Guidelines on Corporate Governance in October 2015 to realize the best possible governance.

In accordance with the Group's Basic Views and Guidelines on Corporate Governance, Shionogi practices fair and transparent management supported by strict compliance, constructive communication with stakeholders, and continuous implementation of measures addressing change in the operating environment.

Basic Views and Guidelines on Corporate Governance
http://www.shionogi.co.jp/en/company/cg/basic.html

Corporate governance structure

Shionogi has adopted a Company with a Board of Auditors governance structure to support efficient management oversight. Under this system, the Group is working to strengthen the audit capabilities of its auditors and the monitoring functions of the Internal Control Department to ensure business execution is based on appropriate management decisions. In order to separate business management and business execution, the directors are responsible for making management decisions in line with the Group's medium- and long-term plans, while the executive officers are responsible for implementing business strategy, resulting in business execution based on rapid and flexible decision-making. Half the Company's directors are outside appointments, and we plan to enhance their supervisory functions further to reinforce management oversight.

Board of Directors

In principle, the Board of Directors meets every month to make decisions on important matters that affect Shionogi's business and to oversee business execution. Aiming to strengthen the board's oversight of business execution, we appointed two outside directors in fiscal 2009 and added another outside director in fiscal 2012 to promote highly transparent and equitable management by drawing on perspectives from outside the Company. In fiscal 2015, we appointed our first female director to the board and increased the number of directors to six in order to strengthen management further and promote diversity. All three outside directors are independent appointments and are tasked with ensuring accountability and a high level of transparency in management.

The Board of Directors is advised by the Nomination Advisory Committee and the Compensation Advisory Committee, which are chaired by outside directors. To ensure that management decisions are equitable and well-informed, these committees carefully assess the aptitude of candidates for director positions, the impact directors have on business management, and the suitability of individuals for certain roles and their respective levels of remuneration.

Board of Auditors

From left: Ikuo Kato, Tsuguoki Fujinuma, Shinichi Yokoyama, Takaoki Fujiwara, Akira Okamoto

Audit framework

To ensure that the directors and each organization in the Company conduct their duties in a legally compliant and appropriate manner, the Company has established systems to enable members of the Board of Auditors and the Internal Control Department, which is responsible for conducting internal audits, to carry out audits of business execution and exchange opinions with the representative directors as required.

The Board of Auditors has five members, comprising two standing members and three outside members. All three outside members of the Board of Auditors are independent appointments. The members of the Board of Auditors attend meetings of key management bodies, such as the Board of Directors and the Corporate Executive Meeting, providing their opinions as necessary. Also, in accordance with corporate auditing standards, members of the Board of Auditors conduct business and accounting audits to verify whether directors and corporate officers responsible for business execution are carrying out their duties in a legally compliant and appropriate manner.

Business execution framework

Shionogi has introduced an executive officer system to support dynamic and flexible business operations, enabling the Group to respond rapidly to significant changes in the operating environment. The Company has also established the Corporate Executive Meeting as a body to discuss business execution. It is composed of directors, auditors and the corporate officers responsible for business execution and meets every week in principle. The Corporate Executive Meeting is a forum for discussing issues related to business execution and important management matters.

Role of Advisory Committees

Nomination Advisory Committee

The Nomination Advisory Committee supports the Board of Directors in an advisory role. Comprised of a majority of outside directors and chaired by an outside director, the Nomination Advisory Committee meets at least once a year to discuss director, corporate auditor and corporate officer candidates proposed by the Company, and assesses each proposal individually based on comprehensive evaluation of each candidate's experience, knowledge, capabilities, and so forth, in order to assess the suitability of candidates in a fair and equitable manner. Its conclusions are then reported to the Board of Directors.
(Meetings held in fiscal 2018: One)

Compensation Advisory Committee

The Compensation Advisory Committee supports the Board of Directors in an advisory role. Comprised of a majority of outside directors and chaired by an outside director, the Compensation Advisory Committee meets at least once a year to discuss the suitability of individuals for certain roles and their respective levels of remuneration, including base remuneration, performance-linked compensation, and stock compensation. Its conclusions are then reported to the Board of Directors.
(Meetings held in fiscal 2018: Two)

Analysis and self-evaluation of the effectiveness of the Board of Directors —summary of results

Shionogi is committed to improving the Board of Directors' effectiveness, and to that end the Board has been conducting a self-evaluation annually since fiscal 2016.
The Board of Directors analyzed and evaluated its effectiveness in fiscal 2018 by conducting questionnaires and interviews of individual directors and corporate auditors, with a focus on "6. Directors and the Board, (1) Framework, (3) Roles and Responsibilities, and (6) Operation" in the Basic Views and Guidelines on Corporate Governance set by the Company. The following is a summary of the results:

Framework

We assess that the Board of Directors has currently secured the necessary framework from the standpoint of various attributes, including expertise and experience, and diversity. However, issues for the future include the election of directors of foreign nationality and the election of female outside directors from the standpoint of further diversity.
The Board of Directors will consider ways to further strengthen the governance framework while taking the Company's business development into account.

Roles and Responsibilities

■ Addressing issues identified in the previous fiscal year

The need to further enhance reporting on management development was identified as an issue in the previous fiscal year, as was the need for supervising the status of management development. Reports were made and opinions exchanged at meetings between outside directors and the president.

To further enhance reporting on compliance and the operation of internal controls, reports on the status of compliance activities are presented twice annually, as of 2018.

■ Issues for the future

Matters identified as issues for the future include enhancement of discussions regarding the medium-term business plan, enhancement of explanations and debate concerning management development (in terms of the selection process and development progression), and further enhancement of compliance frameworks and the content of compliance reporting. The Board of Directors will continue to consider ways to flesh out its roles and responsibilities.

Operation

■ Addressing issues identified in the previous fiscal year

An observation tour of the Shionogi Pharmaceutical Research Center (SPRC) was held to further stimulate discussion at Board of Directors meetings, the need for which was cited as an issue in the previous fiscal year. In addition, with respect to advance briefings on important and highly specialized subjects, the Board of Directors conducted timely advance briefings and considered changing its advance briefing methods.

■ Issues for the future

Matters identified as issues for the future included potential for observation tours to facilities other than the SPRC and improving methods for providing basic information that facilitates better understanding of pharmaceutical companies. The Board of Directors will continue to consider ways to improve its operation.

Based on the above, we conclude that the Board of Directors is operating appropriately and effectively. We will use the results of this self-evaluation as a basis for continuous improvements to make the Board of Directors even more effective.

Remuneration amounts for directors and corporate auditors

Total director remuneration is determined within limits set by resolution of the General Meeting of Shareholders. It encompasses base monthly remuneration, performance-linked bonuses determined by results for the fiscal year and other factors, and restricted stock compensation (medium-term performance-linked and long-term) introduced in fiscal 2018. Outside directors only receive base remuneration.

Base monthly remuneration is determined according to the position and responsibilities of directors with due consideration for the operating environment and global trends. Bonuses are short-term incentives based on a calculation matrix linked to performance, including the achievement of profit targets in each fiscal year. Stock compensation is awarded based on a similar matrix of directors' positions and roles. In particular, medium-term performance-linked compensation is aimed at encouraging directors to pursue continuous enhancement of corporate value by further increasing the linkage between director compensation and medium- and long-term business performance, while at the same time further promoting value sharing with shareholders.

Performance targets include net sales and operating income, driven mostly by new products and core businesses, as well as return on equity (ROE) and the growth rate of total shareholder return (TSR) relative to competitor companies. These indicators were determined after a comprehensive evaluation of factors such as quantitative targets in the medium-term business plan and operational issues, and are premised on the Company achieving the vision laid out in its medium-term business plan, which is to "grow sustainably as a drug discovery-based pharmaceutical company contributing to a more vigorous society through improved healthcare."

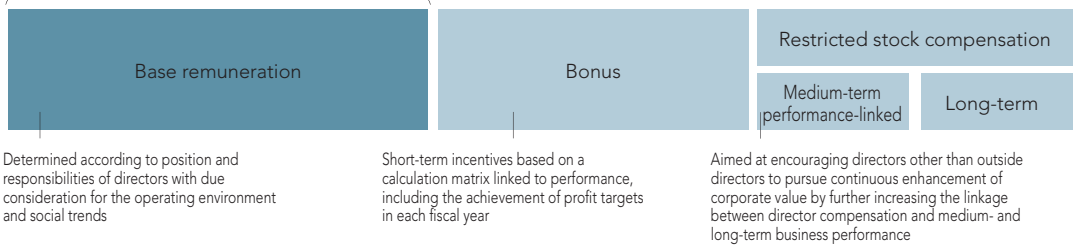
Base remuneration accounted for approximately 75% of total remuneration in fiscal 2013, but less than 50% in the last fiscal year. We aim to further reduce the proportion of base remuneration to about 40%.

Total corporate auditors' remuneration is determined within limits set by resolution of the General Meeting of Shareholders. It is made up entirely of base monthly remuneration.

Shionogi has established a Compensation Advisory Committee to support the Board of Directors in an advisory role. Chaired by an outside director and comprised of a majority of outside directors, this Committee deliberates thoroughly on the subject of directors' remuneration.

Structure of directors' remuneration

Target of roughly 40% of total remuneration



Determined according to position and responsibilities of directors with due consideration for the operating environment and social trends

Short-term incentives based on a calculation matrix linked to performance, including the achievement of profit targets in each fiscal year

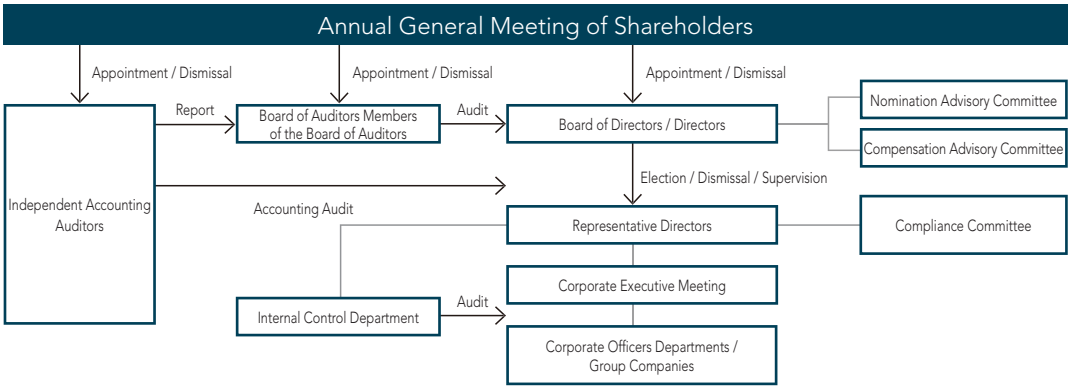
Aimed at encouraging directors other than outside directors to pursue continuous enhancement of corporate value by further increasing the linkage between director compensation and medium- and long-term business performance

Category	Persons remunerated	Amount of remuneration paid					
		Base remuneration (Millions of yen)	Bonuses (Millions of yen)	Stock options*2 (Millions of yen)	Restricted stock compensation		Total (Millions of yen)
					Medium-term performance-linked (Millions of yen)	Long-term (Millions of yen)	
Directors (outside directors among directors)	6(3)	248(43)	153(–)	12(–)	19(–)	40(–)	473(43)
Corporate Auditors*1 (outside auditors among auditors*1)	6(4)	102(43)	–(–)	–(–)	–(–)	–(–)	102(43)
Total	12	350	153	12	19	40	575

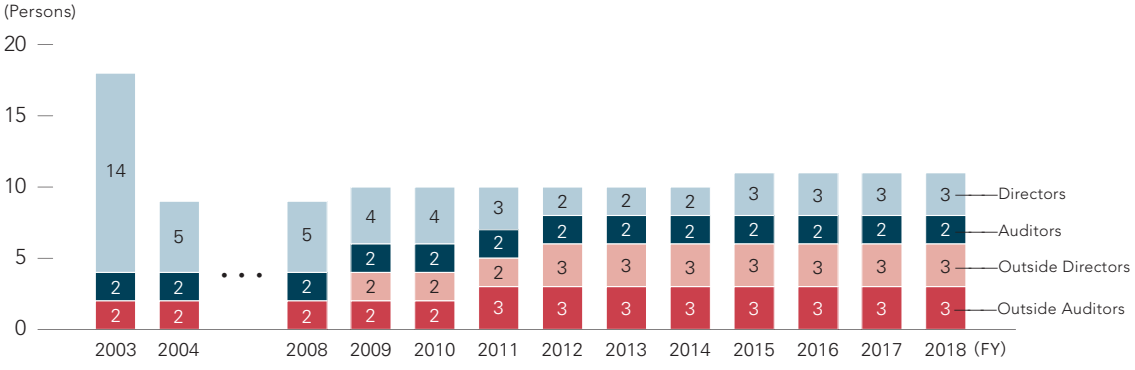
*1 The amount of remuneration paid and persons remunerated include one corporate auditor who retired (deceased) on June 14, 2018.

*2 "Stock options" above is the relevant expense recognized for Fiscal 2018, although no new grants of stock options were made in Fiscal 2018.

Corporate Governance Structure



Corporate Governance Transition



Fiscal 2004
- Number of internal directors reduced to five from fourteen
- Introduction of corporate officer system

Fiscal 2009
- Introduction of an outside director system
- Establishment of Nomination Advisory Committee
- Establishment of Compensation Advisory Committee
- Start of opinion exchanges with auditors

Fiscal 2015
- Information sharing meetings with outside directors
- Advent of female (internal) directors

Fiscal 2017
- Changing composition of Nomination Advisory Committee and Compensation Advisory Committee (majority of members now outside directors)

Interviews with independent outside directors and corporate auditors

Teppei Mogi
Independent Outside Director

Q 1 **Ten years have now passed since your appointment as an independent outside director. Could you comment on how Shionogi has changed in that time?**

During those ten years, Shionogi has developed and launched a steady stream of (mostly proprietary) new drugs, all the while spending less on R&D than major global pharmaceutical companies. As a consequence, Shionogi has evolved into a highly profitable company, in my view. At the time of my appointment, Shionogi faced an enormous challenge in determining how to overcome the so-called "*Crestor* Cliff" (referring to the expiration of patents for the cholesterol-lowering drug *Crestor* in 2016–2017). In the end, the company was able to surmount this crisis through global expansion of its HIV franchise. I believe this was no coincidence, but rather the consequence of a careful plan comprising far-sighted concentration of resources on new drug candidates, and selection of the globalization strategy deemed best suited to Shionogi. Just as expansion of the HIV franchise has buoyed Shionogi earnings, I expect to see a similar contribution from the development and global rollout of *Xofluza*, an flu drug.

On the other hand, while Shionogi has worked tirelessly over those ten years to build a global presence, progress has not always been smooth. It is critical, in my view, that Shionogi continues to launch proprietary drugs both domestically and in overseas (including emerging) markets, with a view to helping more people achieve better health while at the same time generating profits for the company. I believe Shionogi must draw on its experiences thus far to pursue further globalization.

Q 2 **How would you evaluate Shionogi's corporate governance?**

In that ten-year period, companies have become more cognizant of the importance of corporate governance. Shionogi is a front-runner in this respect, which I understand has earned it plaudits from the various stakeholders. The Shionogi Group has appointed a total of six outside officers (both directors and corporate auditors), many with extensive experience at other companies, and these individuals engage in a frank exchange of opinions at Board of Directors meetings. Because of the highly specialized nature of the pharmaceutical industry, it is difficult for these outside officers to contribute directly to the scientific aspect of Shionogi's business. At Board of Directors meetings, though, the outside officers receive regular updates from those directly responsible for operations, and they furthermore participate in debate over important management decisions. Therefore, I believe that Shionogi effectively handles the separation of management and business execution. As a lawyer, I am particularly interested in the company's compliance system. I have observed that top management is constantly impressing upon employees the importance of compliance, and it seems the message is getting through; in my years as an outside officer, I have never once witnessed a major problem from a compliance perspective. There is always room for improvement, though. Going forward I would like to see the company build a global compliance system that is even more effective and more united, extending to overseas Group companies.

Q 3 **Please describe your overall impression of the Board of Directors' management and discussions.**

As noted in my response to the second question, those responsible for business execution make timely and appropriate reports on operational progress and challenges. This ensures candid debate over important management decisions among the Board of Directors, including outside corporate auditors. At Board meetings, I am always astounded at the level of intuition demonstrated by individuals whose experience in top management comes from industries other than pharmaceuticals. Fortunately, earnings have grown steadily over the past ten years and the Board of Directors has never been called on to make choices that could alter the fate of the company. Even if such a situation arose, I am confident that the Board of Directors would be able to reach the appropriate decision after suitable debate.

Q 4 **What are your expectations for Shionogi over the next ten years?**

The business climate surrounding drug companies is by no means favorable, given the global trend toward curtailing healthcare expenditure. For Shionogi to leverage its drug discovery and development capabilities and generate high profits against this backdrop, I think it remains important for the company to single out and selectively invest in leading-edge drug seeds deemed to have long-term potential, with a focus on fields in which Shionogi can excel. In this respect, I have high hopes for the company's numerous peptide discovery programs in the area of medium-sized molecules.

From the standpoint of social contribution, too, I have high expectations for actualization of Shionogi's mission to "protect people from the threat of infectious diseases." In a world in which healthcare is becoming ever more sophisticated, there remain people without access to even the most basic forms of medicine, including prevention of infectious diseases. By contributing to better health for such people, I believe Shionogi can further enhance its global reputation while at the same time increasing corporate value over the longer term. Over the next ten years I think it will be important for the Company to determine how best to pursue further globalization through the worldwide supply of pharmaceuticals bearing the Shionogi name.

Q What role do you envision for yourself in addressing challenges faced by Shionogi?

Keiichi Ando
Independent Outside Director

Stronger corporate governance and adherence to Japan's Stewardship Code have become increasingly important for companies looking to achieve sustained growth, expand corporate value, and discharge their social responsibilities to the full extent. As a leading-edge drug discovery company aspiring to ensure optimum health and realize a safe and secure society, I think Shionogi bears a particularly heavy responsibility. The Company's Board of Directors already is committed to fair and transparent decision-making informed by lively exchanges of ideas and searching questions, and it is actively engaging in improvements to corporate governance. If Shionogi is to achieve ongoing growth and evolution as a drug discovery-based pharmaceutical company, I think it is crucial also that the Company continue to steadily and resolutely implement management strategies and business plans that take a medium- to long-term stance on R&D investment, human resources, and so forth. As an outside director, I aim to draw on my extensive knowledge and wide-ranging experience as an executive in the field of finance and accounting to make an active contribution to fair and transparent management, to the satisfaction of all stakeholders.

Q Could you describe your aspirations as a newly appointed outside director?

Hiroshi Ozaki
Independent Outside Director

I was appointed to the post of outside director on June 18, 2019. In addition to serving as an executive for an integrated energy company based in Kansai, I also have chaired the Osaka Chamber of Commerce and Industry since December 2015, where my contributions have included industry promotion aimed at furthering the growth and development of Osaka and Kansai, support for SMEs, and town planning.

In my view, an outside director's most important mission is to express an independent opinion on whether or not company management is discharging its responsibilities to stakeholders—whether they be customers, communities, employees, or shareholders and investors—in a fair and equitable manner. At the same time, I aim to support the Company in its various initiatives to address future challenges and enhance corporate value.

To ensure that Shionogi retains its reputation as an excellent pharmaceutical company and exemplary member of society, I aim to continue drawing on the experience and expertise I have gleaned to date, to provide appropriate advice with respect to crucial management decisions, and contribute to growing the company and raising management standards.

Tsuguoki Fujinuma
Independent Outside Corporate Auditor

I have been involved with many companies over the years, in the role of accounting auditor as a Certified Public Accountant, and more recently in the role of outside director for several listed companies. As a newly appointed independent outside corporate auditor, my goal this year is to deepen my understanding of Shionogi's basic policy and operations, while at the same time leveraging my professional expertise in finance and accounting to ascertain whether any matters are in particular need of review, whether or not migration to International Financial Reporting Standard (IFRS) is proceeding apace, whether or not information is being appropriately disclosed to shareholders, and whether or not Shionogi initiatives related to Sustainable Development Goals (SDGs) are adequately covered in publications including our annual Integrated Report. From an operational perspective, too, I am keen to assess whether or not the R&D pipeline is being replenished sufficiently, whether or not there is timely recognition of impairment losses on intangible assets, and whether or not the changing times dictate improvement in such areas as risk identification and management, as well as governance and internal controls. To that end, I plan to maintain an open dialog with those involved.

As an outside officer, I think that in meetings of the Board of Directors and Board of Auditors, my role is to say things that internal officers cannot say, and comment on any issues that appear to have gone unnoticed.

Members of Boards (As of June 30, 2019)

Director

Motozo Shiono
Chairman of the Board and Representative Director

Attended all 13 Board of Directors' meetings

▼ Reasons for appointment

Mr. Motozo Shiono became Representative Director and President in 1999. He promoted the First Medium-Term Business Plan and Second Medium-Term Business Plan, and laid a foundation for generating profits. Since becoming Representative Director and Chairman in 2008, he has focused on further enhancing the operation of Board of Directors meetings and contributed substantially to energizing the Board of Directors as Chairman of the Board, such as by fostering an environment that enables outside directors to actively express their opinions and requests, and by enhancing the quality and quantity of information provided. He also has appropriately supervised management's business execution. Shionogi therefore continues to reappoint Mr. Shiono as a Director.

▼ Career summary

January	1972	Joined the Company
June	1984	Director of the Company
April	1987	General Manager, Accounting Department
June	1987	Managing Director of the Company
June	1990	Senior Managing Director of the Company
March	1996	General Manager, Agro., Vet. & Industrial Chem. Division
August	1999	Representative Director and President of the Company and General Manager, Corporate Planning and Division
April	2008	Chairman of the Board of the Company (incumbent)

Isao Teshirogi, Ph.D.
President and CEO

Attended all 13 Board of Directors' meetings

▼ Reasons for appointment

Dr. Isao Teshirogi became Representative Director and President and CEO in 2008. He has pushed forward with global research and development and expansion of overseas business in Europe and Asia to achieve the goals of the Third Medium-Term Business Plan, and secured a medium- to-long-term profit foundation through globally competitive drug discovery capabilities and evolution of the Company's royalty business model. Given the steady achievement of the quantitative targets in the Medium-Term Business Plan SGS2020, which was formulated in fiscal 2014, he carried out an update of SGS2020 in October 2016. As part of that update, he set new quantitative targets from the perspectives of growth, efficiency and shareholder returns. These targets also were achieved ahead of schedule, particularly profit targets. Based on these results, Shionogi continues to reappoint Dr. Teshirogi as a director, in the belief that he can make the Company "grow sustainably as a drug discovery-based pharmaceutical company contributing to a more vigorous society through improved healthcare."

▼ Career summary

April	1982	Joined the Company
January	1999	General Manager, Secretary Office and General Manager, Corporate Planning Department
June	2002	Director of the Company
October	2002	General Manager, Corporate Planning Department
April	2004	Executive Officer and Executive General Manager, Pharmaceutical Research & Development Division
April	2006	Senior Executive Officer and Executive General Manager, Pharmaceutical Research & Development Division
April	2007	Senior Executive Officer
April	2008	Representative Director and President and CEO of the Company (incumbent)

Takuko Sawada
Director, Executive Vice President

Attended all 13 Board of Directors' meetings

▼ Reasons for appointment

Since her appointment as a Director of the Company in 2015, Ms. Takuko Sawada has been responsible for business execution of the Corporate Strategy Division as Senior Vice President of the Corporate Strategy Division and as a Senior Executive Officer. She has also moved the Medium-Term Business Plan Shionogi Growth Strategy 2020 (SGS2020) forward, and played a central role in formulating the update of SGS2020 in October 2016. As of fiscal 2018, she supervises the Pharmaceutical Research Division, Global Development Division, Corporate Quality Management Division, Digital Intelligence Department and other operations in her capacity as Vice President of the Company. Shionogi continues to reappoint Ms. Sawada as Director in order to further strengthen management and promote diversity.

▼ Career summary

April	1977	Joined the Company
April	2002	Executive General Manager, Pharmaceutical Development Division
April	2007	Officer and Executive General Manager, Pharmaceutical Development Division
April	2010	Executive Officer and Executive General Manager, Pharmaceutical Development Division
April	2011	Senior Executive Officer and Executive General Manager, Global Development Office
April	2013	Senior Executive Officer and Senior Vice President, Global Development and, Pharmaceutical Development Division
April	2014	Senior Executive Officer and Senior Vice President, Global Pharmaceutical Development Division
April	2015	Senior Executive Officer and Senior Vice President, Corporate Strategy Division
June	2015	Director of the Company and Senior Executive Officer and Senior Vice President, Corporate Strategy Division
October	2015	Senior Executive Officer and Senior Vice President, Corporate Strategy Division, and General Manager, Corporate Planning Department
April	2016	Senior Executive Officer and Senior Vice President, Corporate Strategy Division
April	2017	Senior Executive Officer and Senior Vice President, Corporate Strategy Division
April	2018	Director of the Company and Executive Vice President (incumbent)

Outside Directors

Teppei Mogi
Independent Outside Director

Attended all 13 Board of Directors' meetings

▼ Reasons for appointment

Mr. Teppei Mogi has not been involved in company management in any way other than serving as outside director or corporate auditor, but he recognizes the corporate responsibility the Company should fulfill and makes fair management decisions, giving priority to legal compliance and social norms from a global perspective from his position as an attorney in international corporate law. Shionogi therefore continues to reappoint Mr. Mogi as an Outside Director. At Board of Directors meetings, he provides legal points and suggestions on protection of intellectual property, raises concerns about business tie-ups, and offers advice on corporate governance, risk management and compliance systems, including those of overseas subsidiaries. As Chairman of the Compensation Advisory Committee, he also makes fair decisions based on an independent and objective viewpoint.

▼ Career summary

April	1989	Registration of Attorney at Law
April	1989	Joined Oh-Ebashi Law Offices
July	1992	Service at Brussels Office of Cleary, Gottlieb, Steen & Hamilton LLP
January	1993	Service at Rotterdam Office of De Brauw Blackstone Westbroek
April	1994	Partner of Oh-Ebashi Law Offices
August	2002	Partner of Oh-Ebashi LPC & Partners (incumbent)
April	2004	Practitioner teacher, Graduate School of Law and Faculty in practical business at The Kwansei Gakuin University Law School (Full-time teacher)
April	2005	Part-time instructor, Graduate School of Law, Kobe University (incumbent)
June	2009	Director of the Company (incumbent)
April	2010	Part-time instructor, Graduate School of Law and Faculty in practical business at The Kwansei Gakuin University Law School
August	2014	Outside Corporate Auditor of NIITAKA Co., Ltd.
June	2015	Outside Corporate Auditor of KURABO INDUSTRIES LTD.
August	2015	Outside Director (Audit & Supervisory Committee member) of NIITAKA Co., Ltd. (incumbent)
June	2016	Outside Director (Audit & Supervisory Committee member) of KURABO INDUSTRIES LTD. (incumbent)

Major concurrent posts

Partner of Oh-Ebashi LPC & Partners

Outside Director (Audit & Supervisory Committee member) of NIITAKA Co., Ltd.

Outside Director (Audit & Supervisory Committee member) of KURABO INDUSTRIES LTD.

Keiichi Ando
Independent Outside Director

Attended all 13 Board of Directors' meetings

▼ Reasons for appointment

Mr. Keiichi Ando has practical experience as a corporate executive at a financial institution and broad insight into finance. He also oversaw highly complex dealings between the national government and the governments of Osaka Prefecture and Osaka City with regard to the airport management business in Kansai, which was at a crossroads, and his experience and insight built the foundation of the concessionaire company Kansai Airports, now a driving force behind the Kansai economy. Mr. Ando continues to be reappointed as an Outside Director as he recognizes the corporate responsibility Shionogi should fulfill and makes management decisions with an emphasis on objectivity and impartiality, without bias in favor of corporate executives or specific interested parties. At Board of Directors meetings, Mr. Ando presents many questions and opinions from the perspective of human resources and the use of assets that are important management resources, and he provides appropriate advice about budget planning and management and capital policies, including investments.

▼ Career summary

April	1976	Joined Sumitomo Bank Limited
April	2003	Executive Officer, Sumitomo Mitsui Banking Corporation
April	2006	Managing Executive Officer, Sumitomo Mitsui Banking Corporation
April	2009	Director and Senior Managing Executive Officer, Sumitomo Mitsui Banking Corporation
April	2010	Representative Director and Deputy President and Executive Officer, Sumitomo Mitsui Banking Corporation
April	2012	Representative Director and President, NEW KANSAI INTERNATIONAL AIRPORT COMPANY, LTD
July	2012	Representative Director and President and CEO, NEW KANSAI INTERNATIONAL AIRPORT COMPANY, LTD.
June	2016	Director of the Company (incumbent)
June	2016	Representative Director and President, GINSEN CO., LTD. (incumbent)
June	2017	Outside Director of Tsubakimoto Chain Co. (incumbent)

Major concurrent posts

Representative Director and President, GINSEN CO., LTD.

Outside Director, Tsubakimoto Chain Co.

Hiroshi Ozaki (New appointment)
Independent Outside Director

▼ Reasons for appointment

Mr. Hiroshi Ozaki has abundant practical experience and wide-ranging knowledge in corporate management and organizational management as a manager of a company based in Kansai. He also serves as chairman of the Osaka Chamber of Commerce and Industry, and worked on industrial promotion and town development aimed at promoting the economic growth of Osaka and Kansai. In the medium-term plan of the Osaka Chamber of Commerce and Industry, he has been focusing on promoting the life science industry since fiscal 2017. Shionogi appointed Mr. Ozaki as an Outside Director as we expect him to draw on this wealth of experience and knowledge to make management judgments with an emphasis on objectivity and neutrality.

▼ Career summary

May	1972	Joined Osaka Gas Co., Ltd.
June	2000	Director, Osaka Gas Co., Ltd.
June	2002	Director and Tokyo Representative, Osaka Gas Co., Ltd., on loan to the Japan Gas Association
June	2005	Managing Director and General Manager of LNG Terminal and Power Generation Business Unit, Osaka Gas Co., Ltd.
June	2007	Managing Director and General Manager of Commercial & Industrial Energy Business Unit, Osaka Gas Co., Ltd.
April	2008	Representative Director and President, Osaka Gas Co., Ltd.
June	2008	Director, Osaka Gas Chemicals Co., Ltd. (incumbent)
June	2009	Representative Director and President, Operating Executive Officer, Osaka Gas Co., Ltd.
June	2009	Director of OGIS-RI Co., Ltd. (incumbent)
June	2011	Outside Director of Asahi Broadcasting Corporation (incumbent)
April	2015	Representative Director and Chairman, Osaka Gas Co., Ltd. (incumbent)
June	2019	Director of the Company (incumbent)

Major concurrent posts

Representative Director and Chairman, Osaka Gas Co., Ltd.

Outside Director, Asahi Broadcasting Corporation

Standing Members of the Board of Auditors

Akira Okamoto

Standing Members of the Board of Auditors

Attended all 13 Board of Directors' meetings
Attended all 8 Board of Auditors' meetings

▼ Reasons for appointment

Mr. Akira Okamoto has served as General Manager of administrative units including the Business Support Center and the Personnel Department, and is well-versed in corporate management. Recently, he has been involved in enhancing the Company's corporate governance and upgrading and operating the internal control system, as General Manager of the Internal Control Department. By leveraging this experience, he is able to provide appropriate advice on management decisions and execution of duties from a neutral point of view as a corporate auditor.

Shionogi therefore continues to reappoint Mr. Okamoto as a Corporate Auditor, as we believe he has the appropriate character and insight to perform an auditor's duties.

▼ Career summary

April	1978	Joined the Company
April	2006	General Manager, Business Support Center
April	2007	General Manager, General Affairs & Personnel Department
April	2008	General Manager, Human Resources Department
April	2011	General Manager, Internal Control Department
June	2015	Standing Member of the Board of Auditors of the Company (incumbent)

Ikuo Kato

Standing Members of the Board of Auditors

Attended all 13 Board of Directors' meetings
Attended all 8 Board of Auditors' meetings

▼ Reasons for appointment

Mr. Ikuo Kato has served as General Manager of the Development Research Laboratories of the Company and as Representative Director and President and Chairman of a subsidiary. He is not only well-versed in research and development, but also has insight into corporate management. As Representative Director and President and Chairman of a subsidiary, he offers comments as necessary on Shionogi's management, and in our judgment, he has the appropriate character and insight to perform the duties of a Corporate Auditor. Shionogi therefore continues to reappoint Mr. Kato as a Corporate Auditor.

▼ Career summary

October	1988	Joined the Company
April	2007	General Manager, Development Research Laboratories
April	2010	General Manager, Drug Development Research Laboratories
April	2011	General Manager, Drug Development Research Laboratories and Representative Director and President, Shionogi TechnoAdvance Research & Co., Ltd.
April	2013	General Manager, Drug Development Research Laboratories and Representative Director and Chairman, Shionogi TechnoAdvance Research & Co., Ltd.
April	2014	Representative Director and Chairman, Shionogi TechnoAdvance Research & Co., Ltd.
June	2016	Standing Member of the Board of Auditors of the Company (incumbent)

Outside Corporate Auditors

Shinichi Yokoyama

Independent Outside Corporate Auditors

Attended all 13 Board of Directors' meetings
Attended all 8 Board of Auditors' meetings

▼ Reasons for appointment

Mr. Shinichi Yokoyama has extensive experience and broad insight as a corporate executive, and makes appropriate recommendations on directors' management decisions and performance of duties from an independent standpoint as a Corporate Auditor. He was appointed as an Outside Corporate Auditor. At meetings of the Board of Directors and Board of Auditors, he makes appropriate recommendations on management decisions and performance of duties mainly related to finance and accounting, from a professional standpoint based on his extensive experience and broad insight as a corporate executive at a financial institution. His insight into pharmaceuticals and the pharmaceutical industry has deepened, and he makes observations indicating the direction the Company should take for the future in a wide range of areas, including advice on the product portfolio and product strategy and opinions on improving the risk management system.

▼ Career summary

April	1966	Joined Sumitomo Life Insurance Company
July	2001	President, Sumitomo Life Insurance Company
June	2003	Outside Corporate Auditor, NEC Corporation
July	2007	Chairman and Representative Director, Sumitomo Life Insurance Company
June	2008	Outside Member of the Board of Auditors of the Company (incumbent)
June	2010	Outside Corporate Auditor, Sumitomo Chemical Co., Ltd.
April	2014	Director, Corporate Advisor, Sumitomo Life Insurance Company
June	2014	Outside Corporate Auditor, Rengo Co., Ltd.
July	2014	Honorary Corporate Advisor, Sumitomo Life Insurance Company
July	2018	Honorary Advisor to the Board, Sumitomo Life Insurance Company (incumbent)

Takaoki Fujiwara
Independent Outside Corporate Auditors

Attended all 10 Board of Directors' meetings
Attended all 6 Board of Auditors' meetings

▼ Reasons for appointment

Based on his extensive experience and broad insight as a representative director of Hankyu Hanshin Holdings, Inc. and as executive of a group company of Hankyu Hanshin Holdings, Inc., we believe that Mr. Takaoki Fujiwara is well qualified to conduct audits on directors' performance of duties from a broad perspective. Shionogi therefore continues to reappoint Mr. Fujiwara as an Outside Corporate Auditor. At meetings of the Board of Directors and Board of Auditors, he provides appropriate advice mainly on compliance, human resources and labor management, and makes appropriate recommendations related to directors' performance of duties from a broad perspective based on his extensive experience and broad insight.

▼ Career summary

April	1975	Joined Hanshin Electric Railway Co., Ltd.
June	2005	Director, Hanshin Electric Railway Co., Ltd.
June	2007	Managing Director, Hanshin Electric Railway Co., Ltd.
April	2011	Representative Director and President, Hanshin Electric Railway Co., Ltd.
June	2011	Director, Hankyu Hanshin Holdings, Inc.
April	2015	Chairman of the Board of Directors and Representative Director, Hanshin Hotel Systems
April	2017	Chairman of the Board of Directors and Representative Director, Hanshin Electric Railway Co., Ltd. (incumbent)
June	2017	Representative Director, Hankyu Hanshin Holdings, Inc. (incumbent)
June	2017	Outside Director, Sanyo Electric Railway Co., Ltd. (incumbent)
December	2017	Director, Hanshin Hotel Systems (incumbent)
June	2018	Outside Member of the Board of Auditors of the Company (incumbent)

Major concurrent posts

Chairman of the Board of Directors and Representative Director, Hanshin Electric Railway Co., Ltd.
Representative Director, Hankyu Hanshin Holdings, Inc.
Outside Director, Sanyo Electric Railway Co., Ltd.
Director, Hanshin Hotel Systems

Tsuguoki Fujinuma (New appointment)
Independent Outside Corporate Auditors

▼ Reasons for appointment

Mr. Tsuguoki Fujinuma has professional expertise in finance and accounting. He has held the important post of Chairman and Advisor of the Japanese Institute of Certified Public Accountants, as well as a number of public offices, and has extensive experience and broad insight as an outside director and outside corporate auditor. He has not been involved in company management in any capacity other than as an outside director or outside corporate auditor, but based on his experience as a certified public accountant, we believe that he is eminently qualified to carry out audits of the Company from the viewpoint of finance and accounting. Shionogi appointed Mr. Fujinuma because we expect that he will reflect this experience in audits of the Company, with respect to the appropriateness of directors' management decisions and execution of duties, from an independent point of view as an Outside Corporate Auditor.

▼ Career summary

April	1969	Joined Horie Morita Accounting Firm
June	1970	Joined Arthur & Young Accounting Firm
May	1986	Partner and Representative Partner of Asahi Shinwa Accounting Firm (now KPMG AZSA LLC)
July	1993	Managing Partner of Ota Showa & Co. (now Ernst & Young ShinNihon LLC) (Resignation in June 2007)
May	2000	President of the International Federation of Accountants
July	2004	Chairman and President of the Japanese Institute of Certified Public Accountants
February	2005	Trustee and Vice Chairman of the IFRS Foundation Trustee
July	2007	Advisor of the Japanese Institute of Certified Public Accountants (incumbent)
August	2007	Outside Director of Tokyo Stock Exchange Group, Inc.
October	2007	Governor of Tokyo Stock Exchange Regulation
April	2008	Specially appointed Professor of Chuo Graduate School of Strategic Management
June	2008	Outside Corporate Auditor of Sumitomo Corporation
June	2008	External Outside Corporate Auditor of Takeda Pharmaceutical Company Limited
June	2008	Outside Director of Nomura Holdings, Inc. Outside Director of Nomura Securities Co., Ltd.
July	2008	Outside Director of Sumitomo Life Insurance Company
April	2010	Visiting Professor at Kansai University
May	2010	Outside Corporate Auditor of Seven & i Holdings Co., Ltd. (incumbent)
April	2015	Fellow and Advisory Board Member at Chuo University Business School (incumbent)
July	2017	Auditor, Chiba Gakuen (incumbent)
June	2019	Outside Member of the Board of Auditors of the Company (incumbent)

Major concurrent posts

Auditor, Chiba Gakuen

Corporate Officers

Senior Executive Officers

Ryuichi Kume, Ph.D.

Yoshiaki Kamoya

Kohji Hanasaki, Ph.D.

John Keller, Ph.D.

Kazuhiro Hatanaka

Toshinobu Iwasaki, Ph.D.

Corporate Officers

Miyuki Hiura

Takeshi Shiota, Ph.D.

Noriyuki Kishida

Ryuichi Kiyama, Ph.D.

Akira Kato, Ph.D.

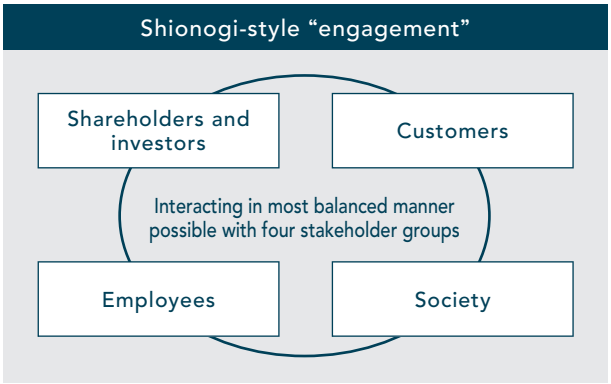
Yasuyoshi Isou, Ph.D.

Stakeholder engagement

In accordance with the Company Policy, we believe it is our social mission to continually discover, develop, and supply useful and safe medicines to promote proper use of medicines, and to help improve the health, medical treatment, and QOL of people around the world. We make every effort in our daily business activities to contribute to all stakeholders.

In the course of these business activities, we believe it is important to always ask ourselves "For whom does a company exist?" and to interact in the most balanced manner possible with our four stakeholder groups: (1) shareholders and investors, (2) customers, (3) society, and (4) employees.

Based on this belief, we have formulated Shionogi's Action Guidelines and the Shionogi Charter of Conduct, which are our codes of conduct, as well as the Shionogi Group Compliance Policy as a standard for compliance. All officers and employees are committed to putting these into practice.



Shionogi Group Compliance Policy
http://www.shionogi.co.jp/en/company/compliance/compliance_02.html

Engagement with shareholders and investors

Shionogi's Disclosure Policy states that as a company trusted widely by society, the Company recognizes that management transparency is one of its most important responsibilities. Based on this recognition, the Company discloses information to all stakeholders in a fair, timely, appropriate and continuous manner.

In our communication with shareholders and investors, the Company subscribes to a spirit of fair disclosure. In addition to disclosing information fairly and at the appropriate time, management and the department in charge of investor relations cooperate in proactive initiatives to promote sustained growth and increase corporate value over the medium and long term.

In addition, we have created a system to encourage closer cooperation among departments, facilitating dialog regarding issues including management strategy, shares, investor relations, finance, and ESG. We also have appointed an officer to oversee this system.

Shionogi Disclosure Policy
http://www.shionogi.co.jp/en/company/policy/disclosure.html

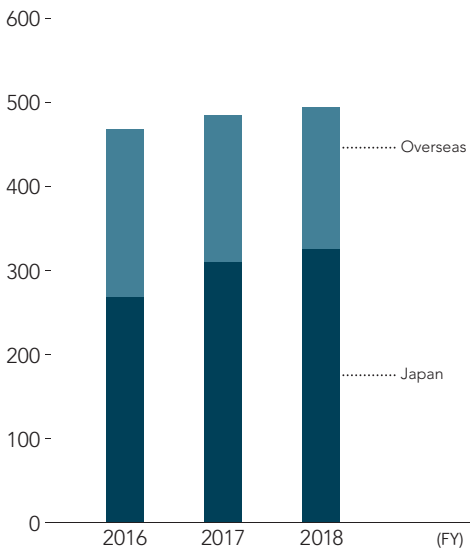
Key IR activities in fiscal 2018

- Results briefings for analysts and institutional investors ..... **Four in total**
- Briefings for analysts and institutional investors ..... **13 in total** (R&D briefing, briefing concerning Sage Therapeutics, and 11 small meetings with analysts and institutional investors)
- Communication with domestic investors..... **Total of 326 companies**
- Communication with overseas investors ..... **Total of 168 companies**
- Participation in conferences hosted by securities companies..... **Five times in total**

Key instances of IR recognition in fiscal 2018

- All-Japan Executive Team (Pharmaceuticals)
  - Most Honored Companies ..... **First**
  - Best CEOs ..... **First**
  - Best IR Professionals ..... **Second**
  - Best IR Programs ..... **First**
  - Best ESG/SRI Metrics ..... **Second**
  - Best Corporate Governance ..... **First**
- Selected among "Companies with Greatest Improvement in IR" in Japan Investor Relations Association's 25th Anniversary Commemorative Award
- Received "Award for Excellence in Corporate Disclosure" from the Securities Analysts Association of Japan (ranked first in the pharmaceuticals sector)
- Selected by Government Pension Investment Fund among companies with "Most-Improved Integrated Reports"

Numbers of communication with investors



Engagement with customers

Provision of information for inquiries

For inquiries related to its products, Shionogi has toll-free telephone numbers and websites for medical professionals as well as consumers and patients. This enables us to quickly provide accurate information regarding the quality, efficacy, and safety of our products.

In fiscal 2018, we received roughly 73,000 inquiries, including approximately 21,000 inquiries concerning *Xofluza*, for which Shionogi received manufacturing and marketing approval on February 23, 2018, after selection as a candidate for Sakigake designation system*1. We believe we assist in patient treatment by responding accurately and quickly to pleas for the urgent provision of information. The Drug Information Center is the contact point for customers. It collects valuable information through inquiries, and shares this with relevant departments to work on improving the quality of products by rectifying problems and strengthening risk management.

Looking ahead, Shionogi will continue to provide information promptly and accurately, in order to contribute to the health of as many patients as possible while further promoting optimal use of information.

*1 Sakigake designation system: A part of Japan's Revitalization Strategy, this system designates pharmaceutical products that are being developed ahead of other countries and have shown exceptional clinical efficacy in the early clinical trial stage. It is aimed at facilitating their early commercialization through various kinds of support.

Engagement with employees

Morale survey measuring employee satisfaction

From 2009, Shionogi periodically conducts a morale survey for the purpose of keeping tabs on employee satisfaction and reflecting the results in personnel policies. In the most recent survey, the employee satisfaction score of 3.93 not only surpassed the benchmark score of 3.68 for leading companies in Japan, but also demonstrated improvement over the previous score of 3.91.

SING of the Year awards

As a means of globally recognizing and awarding activities that embody the Company Policy, we have presented the "SING of the Year" awards every year since 2012. Through this initiative we seek to set in place and promote a "culture of recognition," in order to boost employee motivation and further strengthen our organization.

Exchange of opinions with directors

We hold opinion exchange meetings that aid in resolving employees' concerns by providing an opportunity to communicate directly with directors regarding management policy and issues. These meetings also allow rank-and-file employees to express their opinions, which may then contribute to policy enhancement.

Labor festivals

At Shionogi there is a favorable relationship between the labor union and management. Labor festivals held annually across Japan are attended by many employees including directors, with employees' families also welcome. These events help to foster a sense of unity by promoting communication between labor and management.

Engagement with society

Socie, our social contribution support association

Shionogi established Socie as a social contribution support association in 1997. The Company, its employees and the employee labor union cooperate in supporting Socie members' voluntary social contribution activities. Management and employees work together in carrying out social contribution activities, using funds provided by Shionogi and the labor union at the time Socie was established, and through monthly contributions from employees and the Company. Socie provides assistance to areas affected by earthquakes, storms, volcanic eruptions, and other disasters, as well as to surrounding regions in Japan and overseas. It also makes annual donations to groups that contribute to society, such as the Japanese Red Cross Society and the Japan Guide Dog Association.

Commemorating 2,700th Broadcast of Shionogi Music Fair

Since August 1964, Shionogi has sponsored the music program Shionogi Music Fair, which airs on Saturdays from 6:00 PM to 6:30 PM on a television station associated with Fuji Television Network. To commemorate the 2,700th broadcast in 2018, the show was taped in front of a live audience. Going forward, the Company will continue to sponsor high-quality musical programs that help promote the musical culture of Japan as one way to contribute to society.

Strengthening risk management

Shionogi continues work on building an internal management system in accordance with the Shionogi Group Risk Management Policy established in 2015. With the October 2018 establishment of Shionogi Pharma Co., Ltd. to take charge of manufacturing operations, we redoubled efforts to thoroughly raise awareness about the aforementioned policy among existing group companies as well, in order to facilitate business continuity.

We are also working toward an organizational climate and culture that brings to light risks with potential to threaten business continuity, and ensures the timely reporting to management of all manner of information by Group companies and organizations.

Chaired by the General Manager of the Corporate Strategy Division, which oversees groupwide risk management activities, the Corporate Strategy Meeting is a key discussion body for all manner of risks affecting operations.

In this manner, every Shionogi employee endeavors to protect and make effective use of the Group's valuable business assets, through groupwide risk management activities and a constant and high level of risk awareness.

Shionogi Group Risk Management Policy
http://www.shionogi.co.jp/en/company/policy/riskm.html

Crisis management system

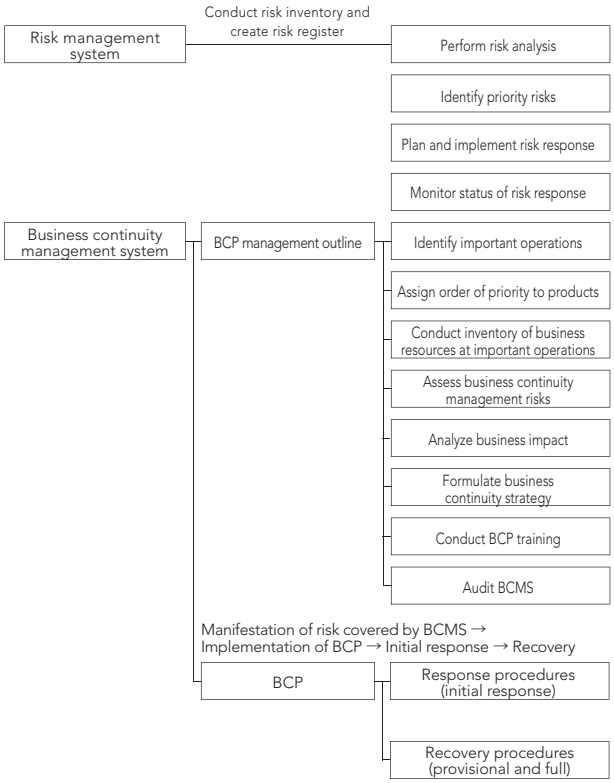
Under our Crisis Management Standard, which serves as the basic policy for crisis management, Shionogi aims to build a comprehensive crisis management system that includes guidelines for various countermeasures and accompanying manuals, and enables rapid response in the event of an emergency. Shionogi places the highest priority on employee safety confirmation in the event of a huge natural disaster, and mandates regular training using the safety confirmation system, as well as stockpiling in case of emergency and reviews of disaster task forces, both centrally and at each business site. In fiscal 2018 there were a number of natural disasters wreaking extensive damage, prompting a further review of disaster task forces (in terms of both organization and manuals), and additional stockpiling.

Business continuity planning (BCP)

Shionogi formulates business continuity plans (BCPs) for each link in the value chain, so that we can continue to fulfill our corporate social responsibility and supply our products and services to medical institutions in a stable manner even in the event of an emergency.

With respect to the supply of pharmaceutical products, in fiscal 2018 we established Shionogi Pharma Co., Ltd. to take charge of manufacturing operations. At that time we conducted a BCP review, resulting in a rebuild of both our risk management system and business continuity management system. In addition to the above, we regularly conduct training at both the management and front-line levels to ensure the ongoing viability of operations.

Overview of risk management system and business continuity management system



Business and other risks

Below, we list and outline the main types of risk that could have a significant impact on Shionogi's operations. The below list does not include all risks to which the Shionogi Group is exposed; other potential risks include political and economic factors affecting business activities, as well as IT security and information management. Forward-looking statements in the text reflect the Group's judgment as of March 31, 2019.

Risk category	Risk description
Systemic and Regulatory Risk	In the pharmaceutical industry, revisions to Japan's National Health Insurance (NHI) system are being considered, including revisions to the NHI drug price system. These trends could affect the results of Shionogi. In addition, tougher Japanese and overseas regulations in areas such as the development and manufacturing of pharmaceuticals could present us with additional expenses or make it difficult for its products to comply with regulations. This could impact our performance.
Risk of Adverse Drug Reactions	Pharmaceuticals entail the risk of unanticipated adverse drug reactions that could lead to the termination of sales, product recalls, and other outcomes that could affect the results of Shionogi.
Pharmaceutical R&D Risk	Pharmaceutical R&D requires substantial commitment of resources and time. In addition, new drugs are subject to numerous uncertainties prior to the start of actual sales.
Intellectual Property Risk	Shionogi uses patents as intellectual property to protect the pharmaceuticals it discovers and generate income from them. However, the various types of intellectual property may be unable to provide adequate protection, or may infringe on the intellectual property of third parties. Furthermore, the expiry of intellectual property rights (patents) of pharmaceuticals developed by Shionogi or the launch of generics after such expiry could affect the results of Shionogi.
Risk of Dependence on Certain Products	*Xofluza* and *Cymbalta* product sales and royalty income from *Tivicay, Triumeq* and *Juluca* roughly account for a combined 48% of net sales (fiscal year ended March 31, 2019). If an unexpected factor were to cause a drop in or the discontinuation of the sales of one of these products, this could impact our performance.
Risk of Alliances with Other Companies	Shionogi engages in diverse forms of alliances with other companies with respect to joint research, development and marketing, and other activities. These alliances include collaboration with research and development projects, in and out licensing of technologies and also marketing. If such collaboration were to either change or cease, it could impact our performance.
Risk of Natural Disasters or Pandemics	The sudden occurrence of a natural disaster, pandemic, or other unforeseen incident could lead to the closure of plants, laboratories or other business sites, which could affect the results of Shionogi.
Capital Market and Foreign Exchange Risk	Fluctuations in stock and foreign exchange markets that exceed the projected range could affect the results and financial position of Shionogi.
Litigation Risk	Through its business activities, Shionogi is exposed to the risk of litigation related to medication side effects, product liability, workplace disputes, fair trading and other issues. Litigation in those and other areas could affect the results of Shionogi.

Ensuring compliance

At Shionogi, compliance remains our No. 1 priority—in short, the basis for company survival. Compliance in Shionogi means compliance not only with laws, rules and regulations, but also with social standards, and it also includes ethical behavior. This approach underpins every aspect of our business. We have published the Shionogi Group Compliance Policy, under which all directors and employees are required to comply with laws and regulations as well as practicing ethical behavior. We also have published both Japanese and English versions of the Shionogi Compliance Handbook, which sets behavioral criteria to be observed in the course of daily operations. In this manner, we are striving to deepen understanding and recognition of the importance of compliance across the Group as a whole.
Our intention is for all employees to consistently hold themselves to the highest ethical standards in order to support sustained growth for Shionogi.

Strict compliance

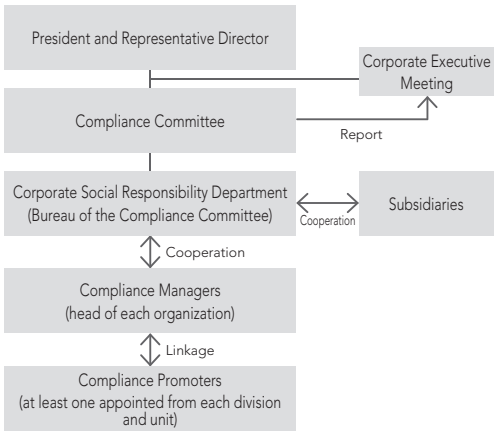
Compliance promotion structure

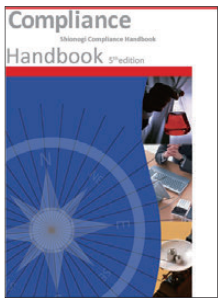
Shionogi promotes compliance in all departments and units through a structure centered on the Compliance Committee, which is chaired by the President and Representative Director and includes among its participants members of the Corporate Executive Meeting.

The Compliance Unit sits within the CSR Department, and provides support for compliance initiatives proposed by the Compliance Committee as well as undertaking a variety of activities including compliance training and surveys. In cooperation with the Compliance Unit, compliance managers (head of each organization) work together with compliance promoters (at least one appointed from each department) on devising compliance initiatives specific to each department or unit. Employees who have served as compliance promoters for at least three years are recognized as "compliance masters" by Shionogi, as a means of further strengthening compliance and raising awareness across the company. In June 2019, a total of 172 employees were recognized as compliance masters.

Concept Chart

Compliance Promotion Structure (As of April 2019)





Shionogi Compliance Handbook

Shionogi Group Compliance Policy
http://www.shionogi.co.jp/en/company/compliance/compliance_02.html

Shionogi Group Anti-Corruption/Anti-bribery Policy
http://www.shionogi.co.jp/en/company/compliance/compliance_03.html

Guidelines for The Prevention of Corruption/Bribery for Shionogi Business Partners
http://www.shionogi.co.jp/en/company/compliance/compliance_04.html

Ethical considerations in animal experiments
http://www.shionogi.co.jp/en/company/policy/animal.html

Clinical Trial Data Transparency Policy
http://www.shionogi.co.jp/en/company/policy/clinical-trial.html

Compliance promotion initiatives

The Compliance Committee meets four times a year to report on and debate compliance-related matters, also preparing reports for the Corporate Executive Meeting and the twice-yearly Board of Directors meetings. Compliance managers work together with compliance promoters on the preparation of compliance risk management (CRM) action plans specific to each department or unit, following a Plan–Do–Check–Act model. Through these activities, Shionogi aims to achieve company wide observation of compliance principles.

In order to identify and address compliance issues, we also conducts regular compliance awareness surveys among directors and employees in the Group. These surveys provide insight into the understanding and penetration of compliance, which can then be reflected in the aforementioned CRM planning, for a solution that encompasses the entire corporate culture.

Shionogi moreover offers regular compliance training for compliance managers and promoters, where Compliance Committee chairman expounds on the importance of compliance while seeking to promote greater awareness and understanding. We also regularly provide rank-specific and role-specific training for division heads and executives as well as personal information management officers, in addition to offering periodic training for all employees on such subjects as information security, pharmaceutical safety, harassment, and bribery.

Establishment of internal reporting system

Shionogi has established an internal reporting system comprising an internal reporting desk and an external reporting desk. We are making every effort to have this system known and used not just by employees but also by third parties, to promote the early discovery as well as prevention and amelioration of compliance violations.

To provide an avenue for consultation on compliance issues, Shionogi furthermore provides all directors and employees with emergency and helpline contact details including those for the reporting desks.

Ensuring high ethical standards and transparency in business activities

Initiatives to improve transparency

Pharmaceutical companies around the world are facing increased scrutiny of their data reliability in clinical trials and transparency for the relation between corporate activities and medical institutions. In addition to complying with laws and ordinances, Shionogi aims to maintain the trust of society by observing the industry's self-imposed norms. As an additional measure, we have formulated original guidelines based on even higher ethical standards. Shionogi has formulated "Transparency Guidelines for the Relationship between Corporate Activities and Medical Institutions," "Transparency Guidelines for the Relationship between Corporate Activities and Patient Associations," and "The Shionogi Code of Practice," in order to maintain high ethical standards and transparency. This includes the appropriate disclosure of funding provided to medical professionals and medical institutions. In the view that fair dealings and fair competition are one of essential elements of compliance, in 2014 the Company also enacted the "Shionogi Group Anti-corruption/Anti-bribery Policy," which is a clear policy statement prohibiting corruption including the payment of bribes. The Company furthermore has formulated "Guidelines for the Prevention of Corruption/Bribery for Shionogi Business Partners," which outlines the compliance requirements to be observed by Shionogi business partners in the hope of further strengthening systems for preventing acts of corruption and/or bribery.

R&D ethics

In the drug discovery research, Shionogi has a policy entitled "Ethical Considerations in Animal Experiments," which sets out to ensure that proper consideration is given to animal welfare by scientifically verifying that animal-use protocols are in accordance with the internationally recognized "principles of the 3Rs (replacement with alternative methods, reduction in the use of laboratory animals, and refinement of methods for reducing pain)." To further enhance the quality of animal experimenters, Shionogi also conducts regular education and training sessions for the employees involved, on appropriate methods for animal experimentation as well as for the breeding and upkeep of experimental animals.

When it comes to clinical development, Shionogi endeavors to ensure the safety of participants in clinical trials while also maintaining transparency through appropriate disclosure in accordance with our Clinical Trial Data Transparency Policy.

Please refer to page 55 for further details on how Shionogi strives to ensure the safety of participants in clinical trials.

Shionogi's business: value chain

In the process of creating new drugs and delivering them to patients, a pharmaceutical company must rely on contributions from multiple business divisions. At Shionogi, every link in the value chain—from research (drug discovery and CMC), to development, manufacturing, and sales—has its own vision and formulates strategies to achieve the goals contained therein, working together when necessary to realize those objectives and in doing so consistently creating new value.

Pharmaceutical Research Division

Vision of Pharmaceutical Research Division

Innovation in drug discovery to meet societal needs

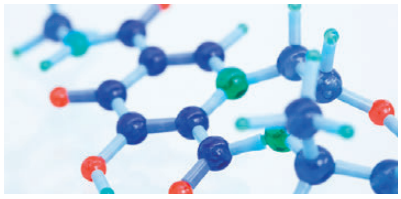
As a drug discovery-based pharmaceutical company, Shionogi considers the original pipeline ratio to be important. At the same time, we believe it is impossible to consistently create better drugs when bound by preconceived ideas. We aim to establish new approaches to drug discovery that draw on various ideas from both inside and outside the Company.

Strategy for achieving our vision

Leverage strength in small molecule drug discovery

keyword 1

Medium molecule drugs



Hopes are high that "medium molecule drugs" such as nucleic acid drugs and peptides will produce the next generation of pharmaceuticals. At Shionogi, we aim to harness the chemical technologies and expertise we have developed in the field of small molecule drug discovery, and apply these also to the discovery of medium molecule drugs.

keyword 2

Open innovation

Shionogi has sought to promote collaborative research with partners, by such means as joining the UK's Cambridge Therapeutic Consortium. We look to accelerate innovation by combining our drug discovery capabilities with the intellectual know-how of academic institutions.

keyword 3

Encouraging sense of adventure in researchers

Innovation tends to be lacking when research is just a job. To instill in our researchers a true sense of adventure, Shionogi evaluates not only research results but also the processes. Furthermore, we have established a novel program dubbed "Y Collaboration" that encourages individuals to independently search out and propose collaborative research partners.

CMC R&D Division

Vision of CMC R&D Division

Research and development of original CMC technology: Creating valuable products meeting societal needs

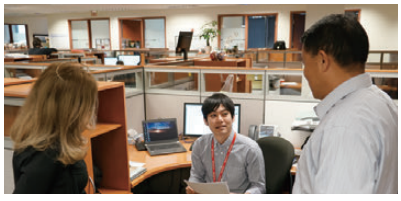
The CMC R&D Division contributes from a total healthcare perspective to the creation of innovative products with potential to fulfil societal medical needs. In order to develop such innovative products, the Division undertakes CMC research and works to acquire new CMC technologies to augment its existing scientific base. By maximizing use of partnerships both inside and outside of Shionogi, the CMC R&D Division strives to bring new value to the healthcare field, transcending traditional paradigms for pharmaceutical development.

Strategy for achieving our vision

Grow the Company by developing better people, technology, and partnerships

keyword 1

Fostering well-rounded employees



Shionogi takes a proactive stance toward education aimed at building well-rounded employees, including an exchange program offering training at Shionogi Inc. in the US, and rotation between different divisions.

keyword 2

Providing new solutions for drug discovery research

Shionogi has been able to use CMC technologies to achieve breakthroughs, improving the body's absorption of chemical compounds that had a pharmacological effect but were difficult to the body to absorb. The CMC R&D Division seeks to continue providing new solutions through involvement from the drug discovery research stage.

keyword 3

Pursuing even higher levels of expertise

Shionogi seeks to create new value through the use of sophisticated CMC technologies for such tasks as developing products that are as effective as possible in meeting patient needs, identifying the synthetic routes best suited to reducing COGs*1, and developing new analytical solutions premised on cutting-edge technology.

*1 COGs: Cost of goods sold

Global Development Division

Vision of Global Development Division

Efficient and consistent development for the good of patients around the world

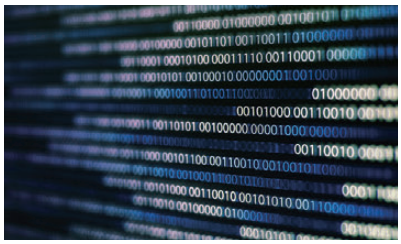
By 2020, we aim to have launched 10 or more products globally. To that end, we seek to maintain a high rate of success in confirmatory (Phase 3) clinical trials by swiftly and accurately identifying compound attributes during early-stage clinical trials, in order to make a science-based go/no-go decision. We furthermore plan to contribute to maximizing product value by extending our data collection horizons beyond what is needed for regulatory submissions, to also include data supporting post-launch marketing.

Strategy for achieving our vision

Build a framework for independently creating and offering pipeline products globally

keyword 1

Use of big data



Further improvement in productivity is key to realizing this vision. Shionogi works constantly on achieving greater efficiency in clinical trials, using real-world data for such purposes as identifying suitable clinical trial participants and creating influenza transmission models.

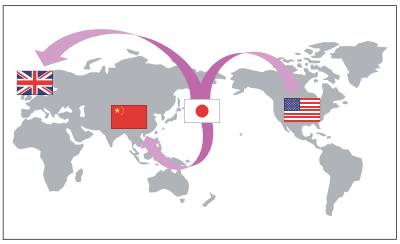
keyword 2

Strengthening global operations

Shionogi is building a global development framework spanning Japan, the US, and Europe, to facilitate speedy and high-quality development. Under a shared global development policy with Shionogi Inc. in the US and Shionogi B.V. in Europe, Shionogi is endeavoring to globalize its operating team.

keyword 3

Global Development Division headquartered in Japan



In an era marked by growth in global clinical trials, the Global Development Division within the parent company in Japan fulfils the important role of managing development projects across our global sites. As headquarters for Shionogi's global operation, the Division is charged with ensuring that the Company's know-how is world-class, and conducting high-quality clinical trials.

Achievements in fiscal 2018: Progress of our next growth drivers and expansion of pipeline and technology through investment toward sustained growth

R&D is an integral part of being a drug discovery-based pharmaceutical company, and in this respect we positioned fiscal 2018 as a year in which to develop growth drivers for 2020 and beyond. Overall, we made steady progress in R&D, aided by active investment in eight high-priority projects. Over and above our typical budget for R&D, we set aside a special budget of ¥20 billion for strategic R&D investment, entering into 10 new strategic collaborations with a view to building a stronger development pipeline for the medium and long term.

Please refer to page 29 for details of strategic collaborations.

Steady progress with eight high-priority projects (as of March 31, 2019)

	Eight high-priority projects	Achievements in fiscal 2018
Infectious Disease	Novel HIV drug candidate	Conducted pre-clinical studies before the start of clinical trials in fiscal 2019
	S-004992 (Tuberculosis)	Conducted pre-clinical studies before the start of phase I clinical trials (China)
Pain/CNS	S-600918 (Refractory/ unexplained chronic cough)	Phase II trials confirmed effect on refractory, unexplained chronic cough (Japan)
	S-637880 (Neuropathic pain)	Phase I clinical trials and a micro-dosing study (Japan)
	S-812217 (Depression)	Phase I clinical trials began in October 2018 (Japan)
Others	S-540956(Nucleic acid adjuvant)	Conducted pre-clinical studies before the start of clinical trials in fiscal 2019
	S-770708 (Idiopathic pulmonary fibrosis)	Phase I clinical trials completed (Japan)
Peptide	Peptide projects	Began five new discovery programs (Infectious disease: 1, Pain/CNS: 2, Others: 2)

Discovery Research: Continuous generation of new development candidates

In fiscal 2018, Shionogi's efforts toward the continuous generation of new development candidates resulted in two discovery success stories. In the field of infectious diseases, we created a novel flu drug candidate, while in frontier areas (disease areas other than the core therapeutic areas of infectious diseases, pain, and CNS disorders), we created a drug candidate for non-alcoholic steatohepatitis (NASH).

CMC Research: Contribution to maximizing value of new development candidates

In CMC research, we succeeded in improvement of API purity and formulation stabilization for cefiderocol, a candidate for the treatment of multidrug-resistant gram-negative bacterial infections, accelerating its development ahead of a planned launch in the US. We also pursued development of a commercial inhalation device in preparation for the launch of S-770108 (pirfenidone inhalant), a treatment candidate for idiopathic pulmonary fibrosis. In trials, our inhaler demonstrated competitive results relative to rival devices from other companies.

Steady advances by development products

In fiscal 2018, Shionogi also progressed development of late-stage development products, achieving steady advances both domestically and overseas.

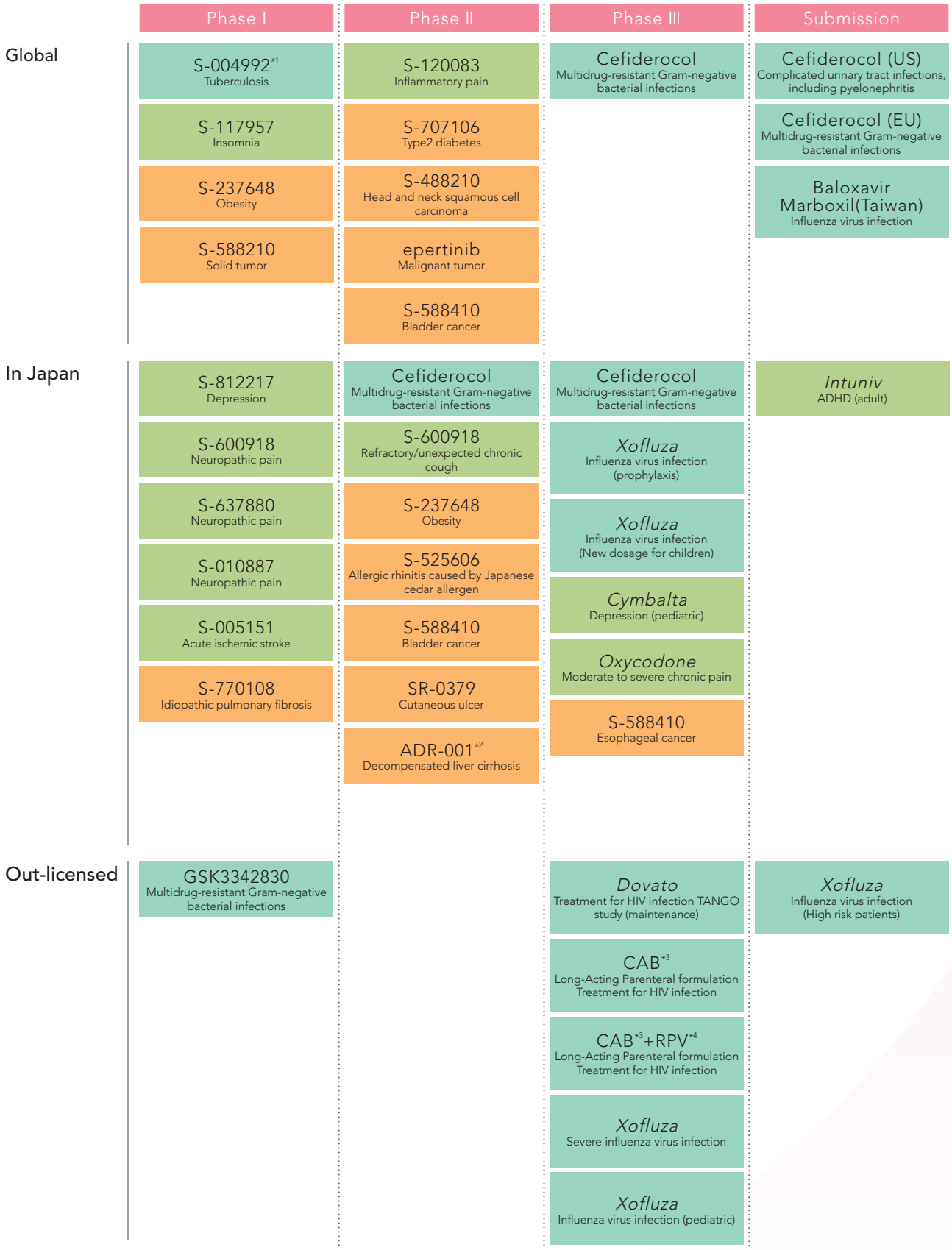
Most notably, we filed for approval of the flu drug *Xofluza* in the US and obtained approval on October 24, two months earlier than planned. As a result, alliance partner Roche was able to begin marketing before the start of the flu season. In addition, positive results were obtained in Phase III clinical trials in influenza patients at high risk for complications, and Roche filed a supplemental New Drug Application in the US.

There was also favorable progress in development of new two-drug HIV regimens licensed out to ViiV Healthcare: *Juluca, Dovato*, and cabotegravir + rilpivirine.

Progress with late-stage development pipeline and other compounds (as of March 31, 2019)

Xofluza Influenza virus infection	US: NDA submission-Approval (October 2018) Japan: Approval of 20mg granule formulation, phase III clinical trial for pediatric granule formulation, phase III clinical trial for prophylaxis
Cefiderocol Multidrug-resistant gram-negative bacterial infections	Accepted for review: US (February 2019), Europe (March 2019) Global phase III clinical trial gram-negative carbapenem resistance in progress, phase III clinical trial for hospital-acquired pneumonia in progress
Rizmoic Opioid-induced constipation	Europe: Approval (February 2019)
Mulpleta Thrombocytopenia	Approval: US (July 2018), Europe (February 2019)
Intuniv ADHD	Japan Additional NDA for use in adult patients (August 2018)
Vyvanse ADHD	Japan: Approval (March 2019)
S-005151 Acute ischemic stroke, Epidermolysis bullosa	Japan: Phase I clinical trial began (acute ischemic stroke, FY2018 Q1)

Pipeline (as of March 31, 2019)



*1 In preparation for Phase I *2 In preparation for Phase I/II *3 CAB: Cabotegravir *4 RPV: Rilpivirine

Human Health Care Division

Vision of Human Health Care Division

Contribute to healthcare through patient-focused collection and provision of information

As a drug discovery-based pharmaceutical company, Shionogi contributes to better health by effectively communicating the value of new products to medical professionals. By endeavoring to do so in a far more productive manner, Shionogi can secure a future for our drug discovery research and development activities. Shionogi strives to meet the nation's increasingly diverse medical needs by supporting the government's community-based healthcare approach through the provision of information tailored to specific communities.

Strategy for achieving our vision

Build highly efficient sales model while at the same time strengthening organization and human resources

keyword 1

Incorporation of IT into sales activities

Basic information on drugs is accessible to all, via channels such as the internet. As such, medical professionals rely on MRs to provide more specialized knowledge. Shionogi strives to enhance the quality of information provided through use of IT to monitor, analyze, and verify MRs' daily activities, to aid in identifying customers' needs in advance.

keyword 2

Support for MRs' provision of information

For MRs to respond to customers' increasingly diverse needs, they require not only information and knowledge, but also the ability to convey this appropriately. At Shionogi, we have established a code of practice for information dissemination, based on new guidelines on ethical drug detailing activities issued by the MHLW in 2018. We are also using these guidelines and code of practice to identify opportunities for improvement, in order to better serve our customers' needs.

keyword 3

Human resource development

In order to develop the human resources needed to facilitate Shionogi's future growth, the Human Health Care Division uses various activities both inside and outside the company to instill in employees critical thinking skills and the ability to take action. We are now seeing employees draw on that experience in their engagement with local communities and customers.

Achievements in fiscal 2018: Growth in domestic business

Concentration of management resources led to increased sales of strategic products, driving domestic sales higher

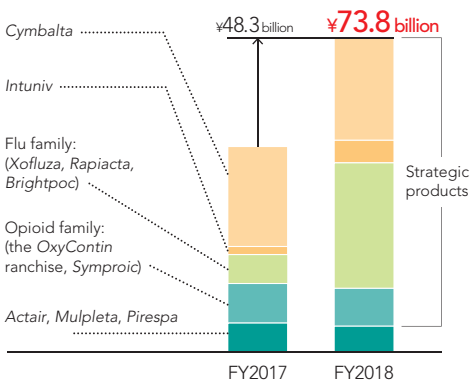
In domestic sales of prescription drugs, Shionogi focused its management resources on strategic products, primarily *Cymbalta*, *Intuniv*, *Xofluza*, the *OxyContin* franchise and *Symproic*. As a result, sales of strategic products were ¥67.8 billion (rising 63.1% year on year) and sales of new products amounted to ¥73.8 billion (rising 52.8% year on year). Sales of *Xofluza*, the flu drug launched in March 2018, were ¥26.3 billion.

Sales growth turned positive on a year-on-year basis in the third quarter because of growth in the aforementioned strategic products along with a diminishing impact from the launch of generic versions of *Crestor* and *Irbetan* in the previous fiscal year.

During fiscal 2018, Shionogi reorganized its domestic sales operations, and set up a "Specialty Product Office" for specialty products which require high-level expertise—namely, *Actair*, *Mulpleta*, *Pirespa*, and the HIV franchise. With that reorganization, Shionogi established a structure that will enhance its expertise in specialty products and allow management resources to be further focused on strategic products with a large market size.

Sales of new products

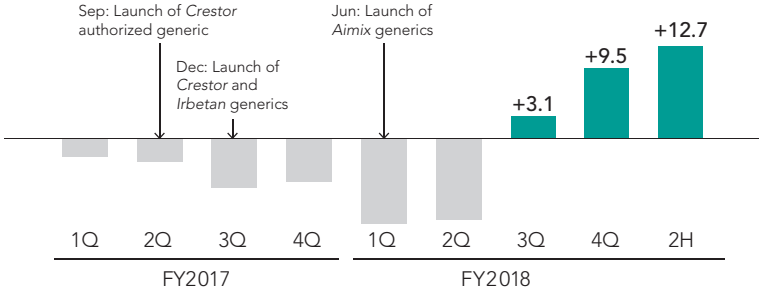
Increased 52.8% YoY



Sales of prescription drugs in Japan (YoY comparison)

(Billions of yen)

The impact of share capture by generic competitors hit a plateau in 1H FY2018 → Sales-growth phase by our own earnings power



Global Business Division

Vision of Global Business Division

To serve the health of people around the world by bringing Shionogi's products to them in the most effective way

At Shionogi, we seek to bring the benefits of Shionogi's innovation to as many people as possible across the globe, either through our own sales capabilities in certain regions, or in partnership with influential local companies.

Strategy for achieving our vision

Maximize product value through a combination of in-house sales, business alliances, and export operations

keyword 1

Operational and strategic support for Group companies overseas

The Global Business Division offers operational support and strategic guidance to our overseas Group companies, with presence in the US, Europe, China, Taiwan, and Singapore, resulting in strong alignment and increased efficiency while encouraging the effective pursuit of the goals of each region.

keyword 2

Support of business alliances in Asia

In China and elsewhere in Asia, Shionogi contributes to better health by actively pursuing alliances with partners with complementary strengths, in order to expedite the development and approval process for our innovative drugs and to encourage their broad availability and accessibility.

keyword 3

Export of drug active ingredients, and bulk and finished products

Shionogi exports products in API, bulk, and finished form, providing patients with access to our products across much of the world.

Achievements in fiscal 2018: Growth of overseas business

Maximizing product value through both in-house sales and alliances

In the US, in April 2019, Shionogi entered a new marketing agreement for *Symproic* with BioDelivery Systems International (BDSI). On our own, Shionogi Inc. launched *Mulpleta* in the US, a treatment for thrombocytopenia in adult patients with chronic liver disease who are scheduled to undergo a procedure.

In Europe, Shionogi obtained regulatory approval for both *Rizmoic* (sold under the brand name *Symproic* in Japan and the US) and *Mulpleta*.

We have entered into multiple sales alliances for *Rizmoic*, with Sandoz responsible for sales in Germany, the UK, and the Netherlands, Molteni Farmaceutici covering Italy and Poland, and Ferrer as our partner in Spain.

In China, too, Shionogi has forged new alliances, licensing both *Mulpleta* and the anticancer agent epertinib to the Eddingpharm Group.

By combining in-house sales with a range of alliances with highly respected partners with complementary capabilities, the Global Business Division seeks to maximize the value of Shionogi products. Our overseas sales have shown growth above the prior-year in all major regions, and rigorous cost management has brought the US business into the black in 2018 after years of operating losses.

Globally speaking, we are continuing to build a foundation for business expansion, with the next key step being progression of cefiderocol through the regulatory approval process in the US and Europe.

Performance in fiscal 2018

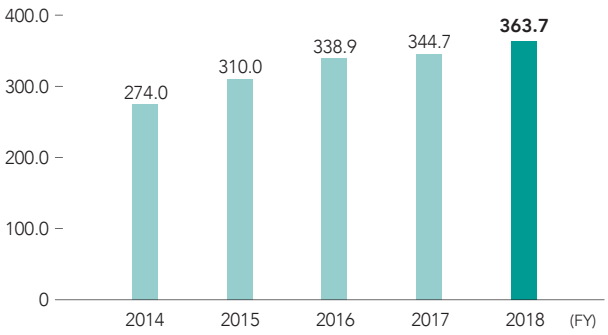
Sustained growth in sales and profits

- Net sales: ¥363.7 billion, for fourth consecutive year of growth

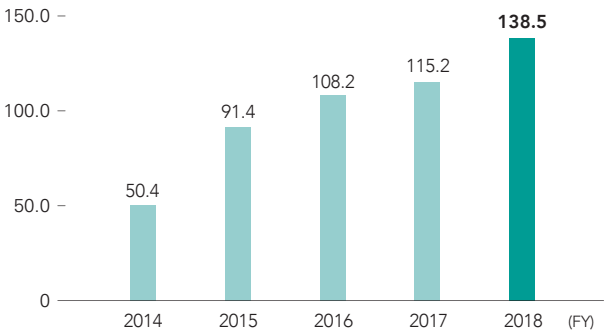
⇒ In fiscal 2018, growth in royalty income and milestone revenues outweighed a decrease in domestic sales of prescription pharmaceuticals, causing net sales to rise for the fourth time in as many years

- Record-high operating income (fourth consecutive year), ordinary income (seventh consecutive year), and profit attributable to owners of parent (third consecutive year)

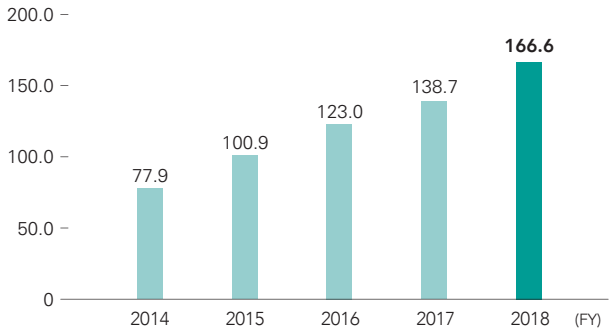
Net sales
(Billions of yen)



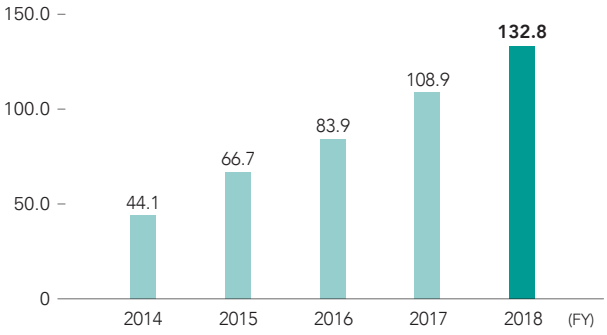
Operating income
(Billions of yen)



Ordinary income
(Billions of yen)



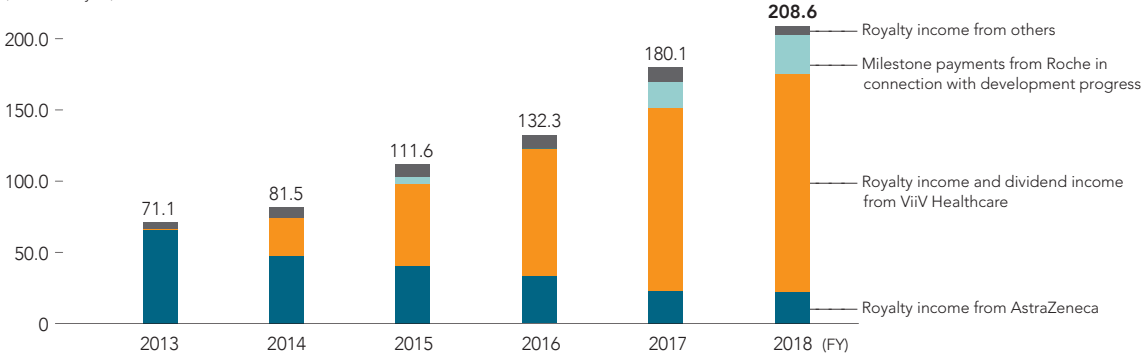
Profit attributable to owners of parent
(Billions of yen)



Growth in royalty income

- Royalty income continued to grow (rising 20.3% year on year) on the back of a steady increase in global sales of HIV franchise products
- Dividend income also grew, underpinned by favorable earnings at ViiV Healthcare's global HIV business
- Shionogi received milestone payments from Roche in connection with progress in global development and approval in the US for the flu drug *Xofluza*

Royalty income and dividend income from ViiV Healthcare
(Billions of yen)



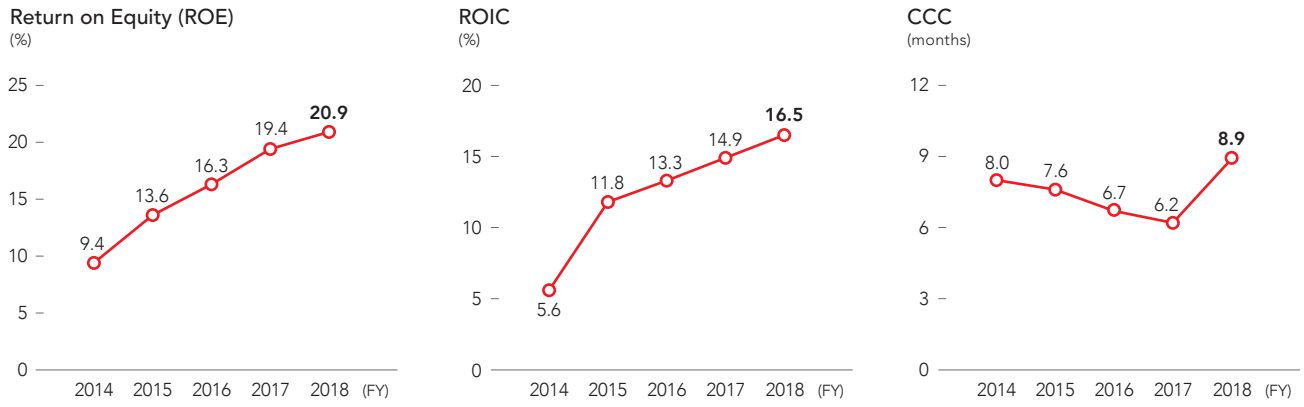
ROE, ROIC, and CCC

- ROE (return on equity) and ROIC (return on invested capital): Steady improvement

⇒ ROE in particular surpassed 20% for the first time

- CCC (cash conversion cycle): Had been decreasing steadily as a result of initiatives to improve conversion periods for receivables and payables and to keep inventories at optimal levels, but recent rapid changes in the product mix saw the CCC extend by 2.7 months to 8.9 months

⇒ Higher sales of new products with a comparatively low cost of sales combined with decreased sales of *Crestor* and the *Irbetan* franchise, which have a high cost of sales, to extend the inventory turnover period and CCC. Based on this change in the product mix, the CCC target for fiscal 2020 was changed from 5.5 months previously to 7.0 months. With cooperation from manufacturing subsidiary Shionogi Pharma Co., Ltd., established in April 2019, the Group is working as one to control inventories and shorten the CCC.

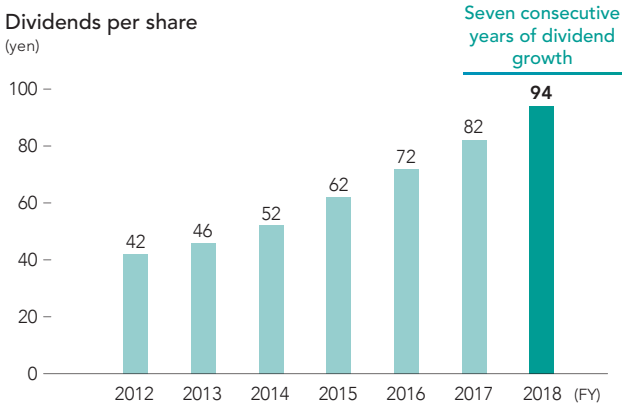


* Return on equity: Profit attributable to owners of parent ÷ (Shareholders' equity + accumulated other comprehensive income) × 100 (%)
* Return on invested capital: After-tax operating income ÷ (Interest bearing debt + Shareholders' equity + Non-controlling interests) × 100 (%)
* Cash conversion cycle: The number of days between investing cash (for raw materials, product purchases, etc.) and the time when that is ultimately converted into cash again. (This indicator is used for capital efficiency.)

Working hard to ensure that shareholders also can experience growth

- Continuous dividend increases
- Flexible share buybacks and retirement of treasury stock

Please refer to page 13 for details of Shionogi's policy on shareholder returns

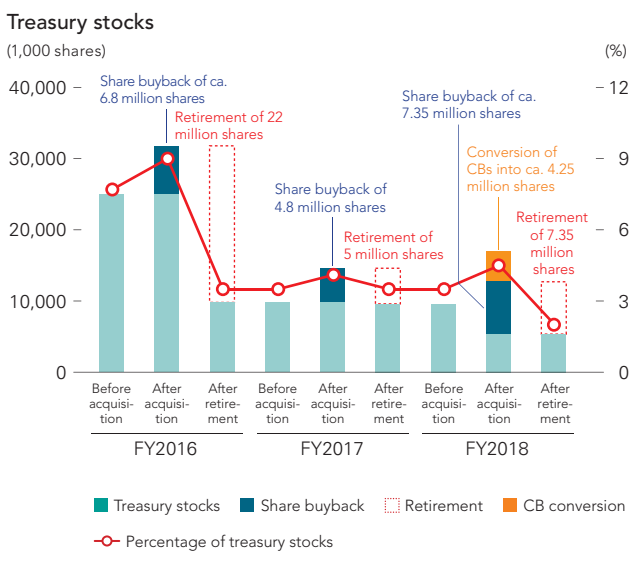


FY2014
· Acquired ¥30 billion of common stock

FY2016
· Acquired ¥35 billion of common stock
· Retired 22 million shares

FY2017
· Acquired ¥29.4 billion of common stock
· Retired five million shares

FY2018
· Acquired ¥50.0 billion of common stock
· Retired 7.35 million shares



11-year summary

	The Second Medium-Term Business Plan "Accelerating toward significant strides" Reinforced R&D and enhanced global operating structure ■ Focused on priority therapeutic areas (infectious diseases, pain and metabolic diseases) ■ Acquired US-based company Sciele Pharma, Inc.		Third Medium-Term Business Plan "SONG for the Real Growth" Progress toward global growth ■ Launched *Osphena* in US ■ Increased sales of eight strategic products in Japan	
	2009	2010	2011	2012
For the years ended March 31:				
Net sales	¥227,512	¥278,503	¥282,350	¥267,275
Cost of sales	70,929	76,264	81,737	77,753
Selling, general and administrative expenses	124,568	149,801	153,721	142,519
Operating income	32,015	52,438	46,892	47,003
Profit before income taxes	30,786	58,541	33,135	41,495
Profit attributable to owners of parent	15,661	38,626	20,027	27,102
Net cash provided by operating activities	29,120	52,902	56,528	54,724
Net cash used in investing activities	(149,056)	(826)	(13,947)	(38,290)
Net cash used in financing activities	105,294	(4,979)	(27,011)	(27,749)
Research and development expenses	52,822	51,808	50,921	53,599
Capital investments	10,875	12,547	17,967	13,233
Depreciation and amortization	13,468	18,048	17,966	16,282
As of March 31:				
Property, plant and equipment, net	¥ 71,812	¥ 62,448	¥ 70,221	¥ 74,282
Total assets	501,853	540,762	523,242	522,162
Total long-term liabilities	114,955	131,956	115,326	92,900
Total net assets	310,094	341,976	328,096	347,198
Per share amounts:				
Profit attributable to owners of parent	¥ 46.75	¥ 115.33	¥ 59.80	¥ 80.93
Net assets	924.43	1,019.71	979.69	1,027.83
Dividend	28	36	40	40
Other:				
Equity ratio	61.7	63.2	62.7	65.9
Return on equity [ROE]	4.8	11.9	6.0	8.1
Payout ratio	59.9	31.2	66.9	49.4

Established footholds in Europe and China	New Medium-Term Business Plan Shionogi Growth Strategy 2020 (SGS2020) Aim to grow as a drug discovery-based pharmaceutical company ■ Identify and channel resources into strategic sales areas and therapeutic areas ■ Growth led by FIC and LIC compounds ■ Continued improvement of business operations						
2013	2014	2015	2016	2017	2018	2019	2019
						Millions of yen	Thousands of U.S. dollars
¥282,904	¥289,717	¥273,991	¥309,973	¥338,890	¥344,667	¥363,722	$3,276,775
78,575	77,993	82,190	74,758	77,777	73,911	54,881	494,424
144,764	149,849	141,437	143,809	152,935	155,537	170,303	1,534,261
59,565	61,875	50,364	91,406	108,178	115,219	138,538	1,248,090
58,307	63,188	82,052	97,453	122,695	137,378	170,343	1,534,622
66,728	40,618	44,060	66,687	83,880	108,867	132,759	1,196,027
59,276	79,496	45,604	102,290	111,903	129,790	145,685	1,312,477
(19,960)	(20,040)	(31,697)	(32,895)	(31,644)	(51,238)	(36,350)	(327,477)
(37,687)	(53,799)	(46,211)	(18,525)	(57,411)	(53,894)	(87,012)	(783,892)
53,021	53,606	48,870	49,788	59,908	59,946	68,325	615,541
11,447	8,962	8,163	9,943	9,659	5,678	7,900	71,171
11,912	12,913	12,673	12,579	13,363	15,973	16,479	148,459
						Millions of yen	Thousands of U.S. dollars
¥ 78,474	¥ 78,977	¥ 77,023	¥ 78,674	¥ 78,788	¥ 75,957	¥ 74,653	$ 672,550
574,882	580,566	595,067	631,600	661,499	711,464	778,741	7,015,685
53,042	33,721	48,427	45,740	44,692	34,057	17,204	154,991
423,633	467,836	478,883	513,877	526,212	604,841	672,430	6,057,928
						Yen	U.S. dollars
¥ 199.25	¥ 121.29	¥ 132.67	¥ 204.83	¥ 259.88	¥ 342.71	¥ 424.31	$ 3.82
1,254.44	1,385.11	1,456.70	1,564.73	1,638.46	1,911.36	2,144.33	19.32
42	46	52	62	72	82	94	0.85
						%	
73.1	79.9	79.7	80.7	79.0	84.5	85.7	
17.5	9.2	9.4	13.6	16.3	19.4	20.9	
21.1	37.9	39.2	30.3	27.7	23.9	22.2	

Notes: 1. U.S. dollar figures have been calculated, for convenience only, at the rate of ¥111.00 = U.S. $1.00, the approximate rate of exchange on March 31, 2019.
2. From the fiscal year ended March 31, 2015, the Company has adopted a new accounting standard for research and development expenses (business research expenses). This change has been reflected in figures for the fiscal year ended March 31, 2014.
3. From the fiscal year ended March 31, 2019, the Company has adopted a new accounting method for tax effect accounting. The change has been reflected in figures for the fiscal year ended March 31, 2015, and subsequent periods.

Consolidated financial statements

Consolidated Balance Sheet

Shionogi & Co., Ltd. and Consolidated Subsidiaries
March 31, 2019

	Millions of yen		Thousands of U.S. dollars (Note 4)
	2019	2018	2019
Assets			
Current assets:			
Cash and cash equivalents (Note 12)	¥ 195,801	¥ 172,401	$ 1,763,973
Short-term investments (Notes 5 and 12)	131,014	92,006	1,180,306
Notes and accounts receivable:			
Affiliates (Note 12)	213	289	1,919
Trade (Note 12)	65,903	53,240	593,721
Other	17,571	16,186	158,297
Allowance for doubtful accounts	(44)	(37)	(396)
	83,643	69,678	753,541
Inventories (Note 6)	40,111	34,637	361,360
Other current assets	11,175	10,782	100,676
Total current assets	461,744	379,504	4,159,856
Property, plant and equipment:			
Land (Notes 7 and 15)	8,438	8,352	76,018
Buildings and structures (Notes 7 and 15)	115,162	118,547	1,037,496
Machinery, equipment and vehicles (Note 8)	85,178	85,229	767,369
Furniture and fixtures	39,979	38,943	360,171
Construction in progress (Note 7)	3,908	1,058	35,207
Accumulated depreciation	(178,012)	(176,172)	(1,603,711)
Property, plant and equipment, net	74,653	75,957	672,550
Investments and other assets:			
Investments in securities (Notes 5 and 12)	143,844	154,333	1,295,892
Investments in affiliates	8,582	1,916	77,315
Asset for retirement benefits (Note 10)	30,722	21,735	276,775
Goodwill (Note 7)	19,258	32,853	173,495
Marketing rights (Note 7)	30,319	38,073	273,144
Long-term prepaid expenses	873	573	7,865
Deferred tax assets (Notes 3 and 11)	1,793	738	16,153
Other assets (Note 17)	6,953	5,782	62,640
Total investments and other assets	242,344	256,003	2,183,279
Total assets (Note 3)	¥ 778,741	¥ 711,464	$ 7,015,685

	Millions of yen		Thousands of U.S. dollars (Note 4)
	2019	2018	2019
Liabilities and net assets			
Current liabilities:			
Notes and accounts payable:			
Affiliates (Note 12)	¥ 711	¥ 738	$ 6,405
Trade (Note 12)	8,732	7,279	78,667
Construction	4,372	2,680	39,387
Current portion of long-term debts (Notes 9 and 12)	921	10,000	8,297
Provision for employees' bonuses	9,059	8,741	81,613
Provision for sales returns	1,428	1,360	12,865
Accrued expenses	12,154	11,094	109,495
Accrued income taxes (Notes 11 and 12)	33,157	18,337	298,712
Other current liabilities (Note 9)	18,573	12,337	167,325
Total current liabilities	89,107	72,566	802,766
Long-term liabilities:			
Long-term debts (Notes 9 and 12)	—	18,492	—
Liability for retirement benefits (Note 10)	11,931	8,097	107,486
Deferred tax liabilities (Notes 3 and 11)	125	3,124	1,126
Long-term accounts payable—other	3,680	3,527	33,153
Other long-term liabilities (Notes 9 and 17)	1,468	817	13,226
Total long-term liabilities	17,204	34,057	154,991
Net assets:			
Shareholders' equity (Note 14):			
Common stock:			
Authorized: 1,000,000,000 shares			
Issued: 316,786,165 shares in 2019 and 324,136,165 shares in 2018	21,280	21,280	191,711
Capital surplus	20,512	20,227	184,793
Retained earnings	639,462	574,392	5,760,919
Less treasury stock, at cost	(28,883)	(36,642)	(260,207)
Total shareholders' equity	652,371	579,257	5,877,216
Accumulated other comprehensive income:			
Net unrealized holding gain on securities	28,928	35,857	260,613
Deferred gain on hedges	748	1,175	6,739
Translation adjustments	(18,371)	(15,331)	(165,505)
Retirement benefit liability adjustments (Note 10)	3,826	(111)	34,468
Total accumulated other comprehensive income, net	15,131	21,590	136,315
Share subscription rights	528	528	4,757
Non-controlling interests	4,400	3,466	39,640
Total net assets (Note 18)	672,430	604,841	6,057,928
Total liabilities and net assets	¥778,741	¥711,464	$7,015,685

See accompanying notes to consolidated financial statements.

Consolidated Statement of Income

Shionogi & Co., Ltd. and Consolidated Subsidiaries
Year ended March 31, 2019

	Millions of yen		Thousands of U.S. dollars (Note 4)
	2019	2018	2019
Net sales (Notes 15 and 19)	¥363,722	¥344,667	$3,276,775
Cost of sales (Notes 6 and 15)	54,881	73,911	494,424
Gross profit	308,841	270,756	2,782,351
Selling, general and administrative expenses (Notes 14 and 15)	170,303	155,537	1,534,261
Operating income	138,538	115,219	1,248,090
Other income (expenses):			
Interest and dividend income	32,328	27,703	291,243
Interest expense	(582)	(558)	(5,243)
Litigation expenses	(791)	(535)	(7,126)
Loss on disposal of property, plant and equipment	(1,364)	(577)	(12,288)
Foreign exchange loss, net	(692)	(1,416)	(6,234)
Gain on sales of investments in securities (Note 5)	17,947	—	161,685
Gain on sales of property, plant and equipment (Note 15)	2,908	—	26,198
Loss on impairment of fixed assets (Note 7)	(13,149)	(520)	(118,459)
Special retirement expenses (Note 15)	(2,849)	—	(25,667)
Loss on disaster (Note 15)	(824)	—	(7,423)
Other, net	(1,127)	(1,938)	(10,154)
	31,805	22,159	286,532
Profit before income taxes	170,343	137,378	1,534,622
Income taxes (Note 11):			
Current	39,988	30,152	360,252
Deferred	(2,951)	(1,563)	(26,585)
	37,037	28,589	333,667
Profit	133,306	108,789	1,200,955
Profit (loss) attributable to:			
Non-controlling interests	547	(78)	4,928
Owners of parent (Note 18)	¥132,759	¥108,867	$1,196,027

See accompanying notes to consolidated financial statements.

Consolidated Statement of Comprehensive Income

Shionogi & Co., Ltd. and Consolidated Subsidiaries
Year ended March 31, 2019

	Millions of yen		Thousands of U.S. dollars (Note 4)
	2019	2018	2019
Profit	¥133,306	¥108,789	$1,200,955
Other comprehensive (loss) income:			
Net unrealized holding (loss) gain on securities	(6,929)	10,815	(62,423)
Deferred (loss) gain on hedges	(427)	1,052	(3,847)
Translation adjustments	(3,261)	4,766	(29,378)
Retirement benefit liability adjustments (Note 10)	3,937	5,151	35,468
Other comprehensive (loss) income (Note 16)	(6,680)	21,784	(60,180)
Comprehensive income	¥126,626	¥130,573	$1,140,775
Comprehensive income (loss) attributable to:			
Owners of parent	¥126,300	¥130,582	$1,137,838
Non-controlling interests	326	(9)	2,937

See accompanying notes to consolidated financial statements.

Consolidated Statement of Changes in Net Assets

Shionogi & Co., Ltd. and Consolidated Subsidiaries
Year ended March 31, 2019

	Millions of yen					
	Common stock	Capital surplus	Retained earnings	Treasury stock, at cost	Total shareholders' equity	Net unrealized holding gain on securities
Balance at April 1, 2017	¥21,280	¥ 20,227	¥508,050	¥(27,111)	¥522,446	¥25,042
Profit attributable to owners of parent	—	—	108,867	—	108,867	—
Dividends	—	—	(24,230)	—	(24,230)	—
Purchases of treasury stock	—	—	—	(29,369)	(29,369)	—
Disposal of treasury stock	—	438	—	1,105	1,543	—
Retirement of treasury stock	—	(18,733)	—	18,733	—	—
Other changes	—	18,295	(18,295)	—	—	10,815
Balance at April 1, 2018	21,280	20,227	574,392	(36,642)	579,257	35,857
Profit attributable to owners of parent	—	—	132,759	—	132,759	—
Dividends	—	—	(27,670)	—	(27,670)	—
Purchases of treasury stock	—	—	—	(50,021)	(50,021)	—
Disposal of treasury stock	—	(1,415)	—	19,175	17,760	—
Retirement of treasury stock	—	(38,605)	—	38,605	—	—
Other changes	—	40,305	(40,019)	—	286	(6,929)
Balance at March 31, 2019	¥21,280	¥ 20,512	¥639,462	¥(28,883)	¥652,371	¥28,928

	Millions of yen						
	Deferred gain on hedges	Translation adjustments	Retirement benefit liability adjustments	Total accumulated other comprehensive income, net	Share subscription rights	Non-controlling interests	Total net assets
Balance at April 1, 2017	¥ 122	¥(20,027)	¥(5,262)	¥ (125)	¥416	¥3,475	¥526,212
Profit attributable to owners of parent	—	—	—	—	—	—	108,867
Dividends	—	—	—	—	—	—	(24,230)
Purchases of treasury stock	—	—	—	—	—	—	(29,369)
Disposal of treasury stock	—	—	—	—	—	—	1,543
Retirement of treasury stock	—	—	—	—	—	—	—
Other changes	1,053	4,696	5,151	21,715	112	(9)	21,818
Balance at April 1, 2018	1,175	(15,331)	(111)	21,590	528	3,466	604,841
Profit attributable to owners of parent	—	—	—	—	—	—	132,759
Dividends	—	—	—	—	—	—	(27,670)
Purchases of treasury stock	—	—	—	—	—	—	(50,021)
Disposal of treasury stock	—	—	—	—	—	—	17,760
Retirement of treasury stock	—	—	—	—	—	—	—
Other changes	(427)	(3,040)	3,937	(6,459)	—	934	(5,239)
Balance at March 31, 2019	¥ 748	¥(18,371)	¥ 3,826	¥15,131	¥528	¥4,400	¥672,430

	Thousands of U.S. dollars (Note 4)					
	Common stock	Capital surplus	Retained earnings	Treasury stock, at cost	Total shareholders' equity	Net unrealized holding gain on securities
Balance at April 1, 2018	$191,711	$ 182,225	$5,174,703	$(330,108)	$5,218,531	$323,036
Profit attributable to owners of parent	—	—	1,196,027	—	1,196,027	—
Dividends	—	—	(249,279)	—	(249,279)	—
Purchases of treasury stock	—	—	—	(450,640)	(450,640)	—
Disposal of treasury stock	—	(12,748)	—	172,748	160,000	—
Retirement of treasury stock	—	(347,793)	—	347,793	—	—
Other changes	—	363,109	(360,532)	—	2,577	(62,423)
Balance at March 31, 2019	$191,711	$ 184,793	$5,760,919	$(260,207)	$5,877,216	$260,613

	Thousands of U.S. dollars (Note 4)						
	Deferred gain on hedges	Translation adjustments	Retirement benefit liability adjustments	Total accumulated other comprehensive income, net	Share subscription rights	Non-controlling interests	Total net assets
Balance at April 1, 2018	$10,586	$(138,117)	$ (1,000)	$194,505	$4,757	$31,225	$5,449,018
Profit attributable to owners of parent	—	—	—	—	—	—	1,196,027
Dividends	—	—	—	—	—	—	(249,279)
Purchases of treasury stock	—	—	—	—	—	—	(450,640)
Disposal of treasury stock	—	—	—	—	—	—	160,000
Retirement of treasury stock	—	—	—	—	—	—	—
Other changes	(3,847)	(27,388)	35,468	(58,190)	—	8,415	(47,198)
Balance at March 31, 2019	$ 6,739	$(165,505)	$34,468	$136,315	$4,757	$39,640	$6,057,928

See accompanying notes to consolidated financial statements.

Consolidated Statement of Cash Flows

Shionogi & Co., Ltd. and Consolidated Subsidiaries
Year ended March 31, 2019

	Millions of yen		Thousands of U.S. dollars (Note 4)
	2019	2018	2019
Operating activities			
Profit before income taxes	¥ 170,343	¥ 137,378	$ 1,534,622
Adjustments for:			
Depreciation and amortization	16,479	15,973	148,459
Amortization of goodwill	2,721	3,036	24,514
Loss on impairment of fixed assets (Note 7)	13,149	520	118,459
(Gain) loss on sales or disposal of property, plant and equipment, net	(1,570)	573	(14,144)
Gain on sales of investments in securities (Note 5)	(17,947)	—	(161,685)
Increase in liability for retirement benefits	521	2,610	4,694
Interest and dividend income	(32,328)	(27,703)	(291,243)
Interest expense	582	558	5,243
Foreign exchange (gain) loss, net	(2,066)	3,071	(18,613)
Other	1,966	(1,344)	17,712
Changes in operating assets and liabilities:			
Notes and accounts receivable—trade and affiliates	(12,431)	5,974	(111,991)
Inventories	(4,832)	6,552	(43,532)
Other current assets	(899)	(1,591)	(8,099)
Notes and accounts payable—trade and affiliates	1,221	(3,811)	11,000
Accrued expenses	(891)	(5,143)	(8,027)
Other current liabilities	5,919	529	53,325
Subtotal	139,937	137,182	1,260,694
Interest and dividends received	30,087	31,773	271,054
Interest paid	(622)	(545)	(5,604)
Income taxes paid	(23,717)	(38,620)	(213,667)
Net cash provided by operating activities	145,685	129,790	1,312,477
Investing activities			
Purchases of short-term investments	(131,730)	(115,740)	(1,186,757)
Proceeds from sales and redemption of short-term investments	93,064	82,272	838,415
Purchases of investments in securities	(3,886)	(2,817)	(35,009)
Proceeds from sales of investments in securities	18,726	2,291	168,703
Purchases of property, plant and equipment	(6,549)	(5,879)	(59,000)
Proceeds from sales of property, plant and equipment	4,261	112	38,387
Purchases of intangible assets	(2,577)	(11,132)	(23,216)
Purchase of investments in capital of affiliates	(5,742)	(100)	(51,730)
Payments for acquisition of businesses	(938)	—	(8,450)
Other	(979)	(245)	(8,820)
Net cash used in investing activities	(36,350)	(51,238)	(327,477)
Financing activities			
Purchases of treasury stock	(50,270)	(29,369)	(452,883)
Cash dividends paid	(27,639)	(24,235)	(249,000)
Repayment and redemption of long-term debts	(10,000)	—	(90,090)
Proceeds from sales of shares of a subsidiary not resulting in change in scope of consolidation	1,020	—	9,189
Other	(123)	(290)	(1,108)
Net cash used in financing activities	(87,012)	(53,894)	(783,892)
Effect of exchange rate changes on cash and cash equivalents	1,077	(1,581)	9,703
Net increase in cash and cash equivalents	23,400	23,077	210,811
Cash and cash equivalents at beginning of year	172,401	149,324	1,553,162
Cash and cash equivalents at end of year	¥ 195,801	¥ 172,401	$ 1,763,973

See accompanying notes to consolidated financial statements.

Notes to Consolidated Financial Statements

Shionogi & Co., Ltd. and Consolidated Subsidiaries
March 31, 2019

1. Basis of Preparation

The accompanying consolidated financial statements of Shionogi & Co., Ltd. (the "Company") and its consolidated subsidiaries (collectively, the "Group") are prepared on the basis of accounting principles generally accepted in Japan, which are different in certain respects as to the application and disclosure requirements of International Financial Reporting Standards, and are compiled from the consolidated financial statements prepared by the Company as required by the Financial Instruments and Exchange Act of Japan.

In preparing the accompanying consolidated financial statements, certain reclassifications have been made to the consolidated financial statements issued domestically in order to present them in a format which is more familiar to readers outside Japan.

In addition, the notes to the consolidated financial statements include certain information which is not required under accounting principles generally accepted in Japan but is presented herein as additional information.

Certain amounts in the prior year's financial statements have been reclassified to conform to the current year's presentation. Such reclassifications had no effect on consolidated profit or net assets.

2. Summary of Significant Accounting Policies

(a) Principles of consolidation and accounting for investments in affiliates

The accompanying consolidated financial statements include the accounts of the Company and all companies controlled directly or indirectly by the Company.

The Company has not applied the equity method to its investments in seven affiliates, including TAKATA Pharmaceutical Co., Ltd., for the purpose of the consolidated financial statements for the year ended March 31, 2019 since the effects on profit and retained earnings on the accompanying consolidated financial statements were immaterial.

Investments in affiliates not accounted for by the equity method are carried at cost.

All significant intercompany accounts and transactions have been eliminated in consolidation.

The fiscal year end of seventeen overseas consolidated subsidiaries is December 31, which is different from that of the Company. These subsidiaries are consolidated by using the financial statements as of and for the year ended December 31. The fiscal year end of one overseas consolidated subsidiary is June 30, which is different from that of the Company. For consolidation purposes, financial statements for this subsidiary are prepared as of and for the year ended December 31. For such overseas consolidated subsidiaries, adjustments have been made for any significant transactions taking place during the period from January 1 to March 31.

(b) Foreign currency translation

All monetary assets and liabilities denominated in foreign currencies are translated into yen at the rates of exchange in effect at the balance sheet date and the gain or loss on each translation is credited or charged to income.

Revenue and expense items arising from transactions denominated in foreign currencies are generally translated into yen at the rates of exchange in effect at the respective transaction dates. Gain or loss on foreign exchange is credited or charged to income in the period in which such gain or loss is recognized for financial reporting purposes.

Assets and liabilities of the overseas consolidated subsidiaries are translated into yen at the rates of exchange in effect at the balance sheet date. Revenues and expenses of the overseas consolidated subsidiaries are translated into yen at the average exchange rates. The components of net assets excluding non-controlling interests are translated at their historical exchange rates. Adjustments resulting from translating the foreign currency financial statements are not included in the determination of profit or loss and are reported as "Translation adjustments" in accumulated other comprehensive income and "Non-controlling interests" in the consolidated balance sheet.

(c) Cash and cash equivalents

Cash and cash equivalents include cash on hand and in banks and other highly liquid investments which are readily convertible to cash subject to an insignificant risk of any change in value and which were purchased with an original maturity of three months or less.

(d) Short-term investments and investments in securities

Securities are classified into three categories: trading securities, held-to-maturity debt securities or other securities. Trading securities, consisting of debt and marketable equity securities, are stated at fair value. Gain and loss, both realized and unrealized, are charged to income. Held-to-maturity debt securities are stated at amortized cost. Marketable securities classified as other securities are carried at fair value with any changes in unrealized holding gain or loss, net of the applicable income taxes, reported as a separate component of net assets. Cost of securities sold is determined by the moving average method. Non-marketable securities classified as other securities are carried at cost determined by the moving average method. Investments in investment partnerships are stated at the amount of net assets attributable to the ownership percentage of the Company.

(e) Money in trust for cash management

Money in trust for cash management is carried at fair value.

(f) Derivatives

Derivatives are carried at fair value.

(g) Inventories

Inventories are principally stated at lower of cost, determined by the average method, or net selling value.

(h) Property, plant and equipment (other than leased assets)

Property, plant and equipment are stated at cost.

Depreciation of property, plant and equipment is calculated by the straight-line method over the estimated useful lives of the respective assets.

The useful lives of property, plant and equipment are summarized as follows:

Buildings and structures	2 to 60 years
Machinery, equipment and vehicles	2 to 17 years

Significant renewals and additions are capitalized at cost. Maintenance and repairs are charged to income as incurred.

(i) Intangible assets (other than leased assets)

Amortization of intangible assets is calculated by the straight-line method over the estimated useful lives of the respective assets.

Expenditures relating to computer software developed for internal use are charged to income as incurred unless these are deemed to contribute to the generation of future income or cost savings. Such expenditures are capitalized as assets and amortized by the straight-line method over their respective estimated useful lives, generally a period of 5 years.

(j) Leased assets

Finance lease transactions that do not transfer ownership are depreciated to a nil residual value over the period of the lease contract using the straight-line method.

(k) Goodwill

Goodwill is amortized over periods of no more than 20 years by the straight-line method.

(l) Research and development expenses

Research and development expenses are charged to income when incurred.

(m) Income taxes

Income taxes are calculated based on taxable income and charged to income on an accrual basis. Certain temporary differences exist between taxable income and income reported for financial reporting purposes which enter into the determination of taxable income in a different period.

(n) Allowance for doubtful accounts

The Company and its consolidated subsidiaries provide an allowance for doubtful accounts at an amount calculated based on their historical experience of bad debts on ordinary receivables plus an additional estimate of probable specific bad debts from customers experiencing financial difficulties.

(o) Provision for employees' bonuses

Provision for employees' bonuses is provided at the estimated amount of bonuses to be paid to the employees in the following year.

(p) Provision for sales returns

The Company provides a reserve for sales returns at the amount of estimated loss expected to be incurred subsequent to the balance sheet date based on a product sales margin and historical sales return ratio. Certain consolidated subsidiaries provide a reserve for sales returns at the amount of estimated loss expected to be incurred subsequent to the balance sheet date based on total product sales and historical sales return ratio.

(q) Retirement benefits

The asset and liability for retirement benefits are provided based on the amount of the projected benefit obligation after deducting plan assets at fair value at the end of the year.

The retirement benefit obligation is attributed to each period by the benefit formula basis.

Prior service cost is amortized as incurred by the straight-line method over a period of 10 years, which is within the estimated average remaining years of service of the eligible employees.

Actuarial differences are amortized from the year following the year in which the gain or loss is recognized, principally by the straight-line method over a period of 10 years, which is within the estimated average remaining years of service of the eligible employees.

Unrecognized actuarial differences and prior service cost, net of tax effect, are recognized as "Retirement benefit liability adjustments" in accumulated other comprehensive income as a component of net assets in the consolidated balance sheet.

(r) Hedge accounting

The Company utilizes derivative transactions for mitigating the fluctuation risks of trade receivable and payable denominated in foreign currencies, forecast transactions and interest rates of loans from financial institutions. Hedging instruments are forward foreign currency exchange contracts, currency options and interest rate swap agreements. Hedged items are trade receivable and payable denominated in foreign currencies, forecast transactions and interest rates of loans from financial institutions.

Gain or loss on derivatives positions designated as hedges is deferred until the loss or gain on the respective underlying hedged items is recognized. Interest-rate swaps which meet certain conditions are accounted for as if the interest rates applied to the swaps had originally applied to the underlying debt (special accounting treatment).

Receivables and payables hedged by forward foreign exchange contracts which meet certain conditions are translated at the corresponding contract rates (allocation method).

The Company evaluates the effectiveness of its hedging activities by comparing the movements of cash flows of hedging instruments and the corresponding movements of cash flows of hedged items. However, with regard to the forward foreign exchange contracts accounted for by the allocation method and the interest-rate swaps accounted for by the special accounting treatment, the evaluation of hedge effectiveness is omitted.

(s) Distribution of retained earnings

Under the Company Act of Japan, the distribution of retained earnings with respect to a given financial period is made by resolution of the shareholders at a general meeting held subsequent to the close of the financial period. The accounts for the period do not reflect such distributions. (Refer to Note 20.)

(t) Accounting standards issued but not yet effective

Accounting Standard and Implementation Guidance on Revenue Recognition

On March 30, 2018, the Accounting Standards Board of Japan (the "ASBJ") issued "Accounting Standard for Revenue Recognition" (ASBJ Statement No.29) and "Implementation Guidance on Accounting Standard for Revenue Recognition" (ASBJ Guidance No.30).

(1) Overview

This is a comprehensive accounting standard for revenue recognition. Specifically, the accounting standard establishes the following five-step model that will apply to revenue from customers:

1. Identify the contracts with a customer
2. Identify the performance obligations in the contracts
3. Determine the transaction prices
4. Allocate the transaction prices to the performance obligations in the contracts
5. Recognize revenue when or as the entity satisfies a performance obligation

(2) Scheduled date of adoption

The Company expects to adopt the accounting standard and the implementation guidance from the beginning of the fiscal year ending March 31, 2021.

(3) Impact of the adoption of accounting standard and implementation guidance

The Company is currently evaluating the effect of the adoption of this accounting standard and the implementation guidance on its consolidated financial statements.

3. Accounting Changes

(1) Change in accounting policies

Revised Practical Solution on Unification of Accounting Policies Applied to Foreign Subsidiaries, etc. for Consolidated Financial Statements and related Practical Solution

Effective from the fiscal year ended March 31, 2019, the Company has early adopted "Practical Solution on Unification of Accounting Policies Applied to Foreign Subsidiaries, etc. for Consolidated Financial Statements" (revised 2018) (PITF No.18) issued by the ASBJ on September 14, 2018.

The impact of this change on the consolidated financial statements was immaterial.

(2) Change in presentation

Partial Amendments to Accounting Standard for Tax Effect Accounting

The Company and its consolidated subsidiaries have adopted "Partial Amendments to Accounting Standard for Tax Effect Accounting" (ASBJ Statement No.28, February 16, 2018) (hereinafter, the "Partial Amendments") from the beginning of the fiscal year ended March 31, 2019. As such, deferred tax assets and deferred tax liabilities are included within investments and other assets and long-term liabilities, respectively, and related income tax disclosures have been expanded.

As a result, deferred tax assets under current assets decreased ¥11,762 million and deferred tax assets under investments and other assets increased ¥726 million in the consolidated balance sheet as of March 31, 2018. In addition, deferred tax liabilities under current liabilities decreased ¥0 million and deferred tax liabilities under long-term liabilities decreased ¥11,036 million.

Deferred tax assets and deferred tax liabilities relating to the same taxation authority were offset against each other, and total assets decreased ¥11,036 million compared to the balance prior to this change.

Also, Note 11 "Income Taxes" in the notes to the consolidated financial statements has been expanded in accordance with Note 8 and Note 9 of Interpretive Notes to Accounting Standard for Tax Effect Accounting. However, comparative information for the year ended March 31, 2018 has not been disclosed in Note 11 in accordance with the transitional provisions set forth in Article 7 of the Partial Amendments.

4. U.S. Dollar Amounts

The translation of yen amounts into U.S. dollar amounts is included solely for convenience, as a matter of arithmetic computation only, at ¥111.00 = U.S. $1.00, the approximate rate of exchange in effect on March 31, 2019. This translation should not be construed as a representation that yen have been, could have been, or could in the future be, converted into U.S. dollars at the above or any other rate.

5. Short-Term Investments and Investments in Securities

(1) Marketable securities classified as other securities at March 31, 2019 and 2018 were as follows:

	Millions of yen		
	2019		
	Carrying value	Acquisition costs	Unrealized gain (loss)
Other securities whose carrying value exceeds their acquisition costs:			
Equity securities	¥ 58,586	¥ 21,550	¥37,036
Debt securities:			
Government bonds, municipal bonds, etc.	16,856	16,017	839
Other securities with maturities	1,513	1,298	215
Other	5,066	5,000	66
Subtotal	82,021	43,865	38,156
Other securities whose carrying value does not exceed their acquisition costs:			
Equity securities	1,046	1,362	(316)
Debt securities:			
Other securities with maturities	37,752	37,752	—
Other	94,000	94,000	—
Subtotal	132,798	133,114	(316)
Total	¥214,819	¥176,979	¥37,840

	Millions of yen		
	2018		
	Carrying value	Acquisition costs	Unrealized gain (loss)
Other securities whose carrying value exceeds their acquisition costs:			
Equity securities	¥ 69,838	¥ 23,866	¥45,972
Debt securities:			
Government bonds, municipal bonds, etc.	16,934	16,022	912
Other securities with maturities	1,536	1,303	233
Other	5,315	5,000	315
Subtotal	93,623	46,191	47,432
Other securities whose carrying value does not exceed their acquisition costs:			
Equity securities	84	890	(806)
Debt securities:			
Other securities with maturities	31,800	31,800	—
Other	92,500	92,500	—
Subtotal	124,384	125,190	(806)
Total	¥218,007	¥171,381	¥46,626

	Thousands of U.S. dollars		
	2019		
	Carrying value	Acquisition costs	Unrealized gain (loss)
Other securities whose carrying value exceeds their acquisition costs:			
Equity securities	$ 527,802	$ 194,144	$333,658
Debt securities:			
Government bonds, municipal bonds, etc.	151,856	144,297	7,559
Other securities with maturities	13,630	11,694	1,936
Other	45,640	45,045	595
Subtotal	738,928	395,180	343,748
Other securities whose carrying value does not exceed their acquisition costs:			
Equity securities	9,423	12,270	(2,847)
Debt securities:			
Other securities with maturities	340,108	340,108	—
Other	846,847	846,847	—
Subtotal	1,196,378	1,199,225	(2,847)
Total	$1,935,306	$1,594,405	$340,901

Because no quoted market price is available and it is extremely difficult to determine the fair value, unlisted stocks of ¥62,289 million ($561,162 thousand) and ¥60,627 million at March 31, 2019 and 2018, respectively, are not included in the above table.

(2) Proceeds from sales of, and gross realized gain on, other securities for the year ended March 31, 2019 are as follows:

	Millions of yen	Thousands of U.S. dollars
	2019	2019
Proceeds from sales	¥18,726	$168,703
Gross realized gain	17,947	161,685

There were no sales of other securities for the year ended March 31, 2018.

(3) Loss on devaluation of investments in securities
Loss on devaluation of investments in securities is recorded for securities whose fair value has declined by 30% or more if the decline is deemed to be irrecoverable considering the financial position of the securities' issuers and other factors.

The Company recognized loss on devaluation of investments in securities of ¥84 million ($757 thousand) and ¥796 million for the years ended March 31, 2019 and 2018, respectively.

6. Inventories

Inventories at March 31, 2019 and 2018 were as follows:

	Millions of yen		Thousands of U.S. dollars
	2019	2018	2019
Merchandise	¥ 5,603	¥ 4,929	$ 50,477
Finished goods	10,347	7,193	93,216
Semi-finished goods and work in process	10,064	9,588	90,667
Raw materials and supplies	14,097	12,927	127,000
	¥40,111	¥34,637	$361,360

Cost of sales included loss on devaluation of inventories of ¥(292) million ($(2,631) thousand) and ¥1,418 million for the years ended March 31, 2019 and 2018, respectively.

7. Loss on Impairment of Fixed Assets

The assets for business use are grouped based on their corresponding management segment, such as product lines. Assets available for rent and idle assets are grouped individually.

The Group recognized loss on impairment of fixed assets for the year ended March 31, 2019 as follows:

			Millions of yen	Thousands of U.S. dollars
Location	Use	Classification	2019	2019
United States of America	—	Goodwill	¥11,943	$107,595
Netherlands	Marketing rights for prescription drugs	Marketing rights	460	4,144

With regard to the goodwill of the U.S. subsidiary, Shionogi INC., the Group reduced the book value to the recoverable value due to downward adjustments to expected profitability that was initially anticipated due to the deterioration of the environment in the U.S. business, and the reduction was recorded as an impairment loss.

With regard to the marketing rights of the Netherlands subsidiary, Shionogi B.V., the Group reduced the book value to the recoverable value due to a decline in profitability of the items related to ethical pharmaceutical products, and the reduction was recorded as an impairment loss.

			Millions of yen	Thousands of U.S. dollars
Location	Use	Classification	2019	2019
Settsu Plant Building No.301 (Settsu, Osaka Prefecture)	Idle assets	Buildings, etc.	¥746	$6,720

In line with the maintenance of the Settsu plant, the Company made the decision to remove idle assets at the Settsu plant. As a result, the Company recorded a loss on impairment of fixed assets in an amount equal to the carrying value of these idle assets. The significant component of these idle assets was buildings in the amount of ¥678 million ($6,108 thousand).

The Group recognized loss on impairment of fixed assets for the year ended March 31, 2018 as follows:

Location	Use	Classification	Millions of yen 2018
Japan	Marketing rights for a prescription drug, etc.	Marketing rights, etc.	¥204

Due to the termination of a sales collaboration agreement with Allergan Japan K.K., the Company recognized a loss on impairment equal to the carrying value of the corresponding marketing rights, etc. for a product, which the Company and Allergan Japan K.K. used to jointly sell.

Location	Use	Classification	Millions of yen 2018
Kanegasaki Dormitory (Isawa, Iwate Prefecture)	Idle assets	Land, Buildings, etc.	¥129
Kuise Office Building No.500 (Amagasaki, Hyogo Prefecture)	Idle assets	Buildings, etc.	115
Settsu Plant (Settsu, Osaka Prefecture)	Idle assets	Construction in progress	72

The Company made a decision to abolish a dormitory for unmarried employees as a part of the employee welfare system. As a result, the Company recorded a loss on impairment of fixed assets in an amount equal to the carrying value of these idle assets. The significant components of these idle assets were buildings in the amount of ¥67 million and land in the amount of ¥60 million.

The Company made a decision to demolish and remove the building No.500 at Kuise office as a part of a reorganization of business offices. As a result, the Company recorded a loss on impairment of fixed assets in an amount equal to the carrying value of these idle assets. The significant component of these idle assets was buildings in the amount of ¥104 million.

The Company classified facilities for formulation research and production at Settsu plant as idle assets because these facilities were not in use due to a change in the business plan and were not expected to be used in the future. As a result, the Company recorded a loss on impairment of fixed assets in an amount equal to the carrying value of these idle assets.

8. Leases

The Group has entered into finance lease contracts which do not transfer the ownership of the leased assets. The main components of such finance leases are office automation equipment and security devices classified as machinery, equipment and vehicles in the consolidated balance sheet.

The Group also has entered into non-cancellable operating lease contracts. Future minimum lease payments subsequent to March 31, 2019 under non-cancellable operating leases are summarized as follows:

Years ending March 31,	Millions of yen 2019	Thousands of U.S. dollars 2019
2020	¥ 326	$ 2,937
2021 and thereafter	1,501	13,522
	¥1,827	$16,459

9. Long-Term Debts and Lease Obligations

Long-term debts and lease obligations at March 31, 2019 and 2018 consisted of the following:

	Millions of yen 2019	Millions of yen 2018	Thousands of U.S. dollars 2019
Unsecured loans from banks and financial institutions due through 2019	¥ —	¥ 10,000	$ —
Zero coupon convertible bonds due in 2019	921	18,492	8,297
Finance lease obligations (included in "other current liabilities" and "other long-term liabilities")	879	177	7,919
	1,800	28,669	16,216
Less current portion	(1,185)	(10,083)	(10,675)
	¥ 615	¥ 18,586	$ 5,541

The aggregate annual maturities of long-term debts and lease obligations subsequent to March 31, 2019 are summarized as follows:

Years ending March 31,	Millions of yen	Thousands of U.S. dollars
2020	¥1,185	$10,675
2021	240	2,162
2022	211	1,901
2023	164	1,478
	¥1,800	$16,216

10. Retirement Benefits

(1) Overview

The Company has a defined benefit pension plan known as a "cash balance plan," which allows pension benefits to fluctuate in accordance with market interest rates, and it also has a lump-sum payment plan and a defined contribution pension plan. Certain domestic consolidated subsidiaries have lump-sum payment plans and defined contribution pension plans. In certain cases, the Group may also pay special retirement benefits that are not subject to any actuarial calculations.

(2) Defined benefit plans for the years ended March 31, 2019 and 2018

The changes in retirement benefit obligations are outlined as follows:

	Millions of yen 2019	Millions of yen 2018	Thousands of U.S. dollars 2019
Retirement benefit obligations at beginning of the year	¥71,055	¥75,211	$640,134
Service cost	1,856	1,906	16,721
Interest cost	599	634	5,396
Actuarial differences	(43)	(739)	(387)
Retirement benefits paid	(5,703)	(5,957)	(51,378)
Retirement benefit obligations at end of the year	¥67,764	¥71,055	$610,486

The changes in plan assets at fair value are outlined as follows:

	Millions of yen		Thousands of U.S. dollars
	2019	2018	2019
Plan assets at fair value at beginning of the year	¥84,693	¥84,037	$763,000
Expected return on plan assets	2,117	2,101	19,072
Actuarial differences	3,294	2,309	29,676
Contributions paid by the Group	994	995	8,955
Retirement benefits paid	(4,543)	(4,749)	(40,928)
Plan assets at fair value at end of the year	¥86,555	¥84,693	$779,775

The balance of retirement benefit obligation and plan assets at fair value, and liabilities and assets recognized in the consolidated balance sheets are outlined as follows:

	Millions of yen		Thousands of U.S. dollars
	2019	2018	2019
Funded retirement benefit obligations	¥ 65,935	¥ 69,101	$ 594,009
Plan assets at fair value	(86,555)	(84,693)	779,775
	(20,620)	(15,592)	(185,766)
Unfunded retirement benefit obligation	1,829	1,954	16,477
Net asset for retirement benefits in consolidated balance sheet	¥(18,791)	¥(13,638)	$(169,289)
Liability for retirement benefits	¥ 11,931	¥ 8,097	$ 107,486
Asset for retirement benefits	(30,722)	(21,735)	(276,775)
Net asset for retirement benefits in consolidated balance sheet	¥(18,791)	¥(13,638)	$(169,289)

The components of retirement benefit expenses for the years ended March 31, 2019 and 2018 are outlined as follows:

	Millions of yen		Thousands of U.S. dollars
	2019	2018	2019
Service cost	¥ 1,856	¥ 1,906	$ 16,721
Interest cost	599	634	5,396
Expected return on plan assets	(2,117)	(2,101)	(19,072)
Amortization:			
Actuarial differences	2,540	4,579	22,883
Prior service cost	(204)	(204)	(1,838)
Retirement benefit expenses	¥ 2,674	¥ 4,814	$ 24,090

The components of retirement benefit liability adjustments recognized in other comprehensive income, before tax effects, are outlined as follows:

	Millions of yen		Thousands of U.S. dollars
	2019	2018	2019
Prior service cost	¥ (204)	¥ (204)	$ (1,838)
Actuarial differences	5,877	7,627	52,946
Total	¥5,673	¥7,423	$51,108

The components of retirement benefit liability adjustments recognized in accumulated other comprehensive income, before tax effects, are outlined as follows:

	Millions of yen		Thousands of U.S. dollars
	2019	2018	2019
Unrecognized prior service cost	¥(1,022)	¥(1,226)	$ (9,207)
Unrecognized actuarial differences	(4,491)	1,386	(40,460)
Total	¥(5,513)	¥ 160	$(49,667)

The percentage composition of each major category of plan assets at fair value at March 31, 2019 and 2018 was as follows:

Asset class	2019	2018
Equity securities	9%	25%
General accounts controlled by life insurance companies	25	23
Debt securities	29	26
Other	37	26
Total	100%	100%

As of March 31, 2019 and 2018, 14% and 26%, respectively, of total plan assets were included in retirement benefit trusts established for corporate pension plans.

Policy for determining expected long-term rate of return on plan assets

The expected long-term rate of return on plan assets is derived as a combination of the portfolio allocation of current and expected plan assets, and the forward-looking view of the long-term expected rates of return from multiple plan assets at present and in the future.

The assumptions used in accounting for the defined benefit plans for the years ended March 31, 2019 and 2018 are as follows:

	2019	2018
Discount rate	0.8%	0.8%
Expected long-term rate of return on plan assets (Weighted average)	2.5%	2.5%
Expected rate of salary increase (Weighted average)	3.5%	3.5%

(3) Defined contribution plans for the years ended March 31, 2019 and 2018

The total contributions paid by the Group to the defined contribution plans were ¥1,590 million ($14,324 thousand) and ¥1,584 million for the years ended March 31, 2019 and 2018, respectively.

11. Income Taxes

Income taxes applicable to the Company and its domestic consolidated subsidiaries comprise corporation tax, inhabitants' taxes and enterprise taxes which, in the aggregate, resulted in statutory tax rates of approximately 30.6% and 30.8% for the years ended March 31, 2019 and 2018, respectively.

The overseas subsidiaries are subject to the income taxes of the respective countries in which they operate.

The effective tax rates for the years ended March 31, 2019 and 2018 differ from the above statutory tax rate for the following reasons:

	2019	2018
Statutory tax rate	30.6%	30.8%
Expenses not deductible for income tax purposes	0.0	0.1
Dividends not taxable for income tax purposes	(3.3)	(4.1)
Amortization of goodwill	2.5	0.5
Tax credits	(6.4)	(6.1)
Inhabitants' per capita taxes	0.1	0.1
Difference in statutory tax rates of overseas subsidiaries	(1.7)	(2.0)
Increase in valuation allowance	1.3	2.4
Other	(1.4)	(0.9)
Effective tax rates	21.7%	20.8%

The tax effects of temporary differences at March 31, 2019 and 2018 which gave rise to significant deferred tax assets and liabilities are presented below:

	Millions of yen		Thousands of U.S. dollars
	2019	2018	2019
Deferred tax assets:			
Tax loss carryforwards (Note)	¥ 27,298	¥ 23,064	$ 245,928
Adjustments to the carrying value of investments in a subsidiary	12,462	12,462	112,270
Research and development expenses	9,409	9,172	84,766
Intangible assets	3,219	3,249	29,000
Provision for employees' bonuses	2,619	2,485	23,595
Accrued expenses and other current liabilities	1,105	935	9,955
Loss on revaluation of investments in securities	2,442	2,642	22,000
Accrued enterprise taxes	1,786	925	16,090
Provision for sales returns	399	344	3,595
Other	7,052	9,486	63,531
Total gross deferred tax assets	67,791	64,764	610,730
Valuation allowance for tax loss carryforwards (Note)	(27,298)	—	(245,928)
Valuation allowance for deductible temporary differences	(23,891)	—	(215,234)
Total valuation allowance	(51,189)	(47,827)	(461,162)
Total deferred tax assets	16,602	16,937	149,568
Deferred tax liabilities:			
Unrealized gain on other securities	(8,913)	(11,575)	(80,297)
Reserve for advanced depreciation of property, plant and equipment	(1,685)	(1,741)	(15,180)
Investments in securities	(1,283)	(1,283)	(11,560)
Asset for retirement benefits	(1,926)	(1,321)	(17,351)
Other	(1,127)	(3,403)	(10,153)
Total deferred tax liabilities	(14,934)	(19,323)	(134,541)
Net deferred tax assets (liabilities)	¥ 1,668	¥ (2,386)	$ 15,027

Note: A breakdown of the tax loss carryforwards and valuation allowance by expiry date as of March 31, 2019 is as follows:

	Millions of yen				
	2019				
	Due in 1 year or less	Due after 1 year through 3 years	Due after 3 years through 5 years	Due after 5 years	Total
Tax loss carryforwards (*)	¥ —	¥ —	¥ 332	¥ 26,966	¥ 27,298
Valuation allowance	—	—	(332)	(26,966)	(27,298)
Deferred tax assets	¥ —	¥ —	¥ —	¥ —	¥ —

	Thousands of U.S. dollars				
	2019				
	Due in 1 year or less	Due after 1 year through 3 years	Due after 3 years through 5 years	Due after 5 years	Total
Tax loss carryforwards (*)	$ —	$ —	$ 2,991	$ 242,937	$ 245,928
Valuation allowance	—	—	(2,991)	(242,937)	(245,928)
Deferred tax assets	$ —	$ —	$ —	$ —	$ —

(*) The tax loss carryforwards in the above table are measured using the statutory tax rates.

12. Financial Instruments

(1) Overview

(a) Policy for financial instruments

The Group obtains necessary funding principally by bank borrowings and bond issuance under the business plan for its main business for the production and sales of pharmaceuticals. Temporary surplus funds are managed by low-risk financial assets. Derivatives are utilized for mitigating risks described in the latter part of this note and not utilized for speculative purpose.

(b) Types of financial instruments and related risk

Trade receivables, notes and accounts receivable, are exposed to the credit risk of customers. Trade receivables denominated in foreign currencies are exposed to the fluctuation risk of foreign currencies. Short-term investments and investments in securities are exposed to fluctuation risk of market price.

Trade payables, notes and accounts payable, are due within one year. Certain trade payables denominated in foreign currencies for the import of raw materials are exposed to the fluctuation risk of foreign currencies. Loans and bonds are utilized principally for necessary financing under the business plan and those maturity dates are due in 1 year, at the longest, subsequent to March 31, 2019.

Derivative transactions are made for hedging foreign currency fluctuation risk of trade receivables, trade payables, forecasted transactions and intercompany loans receivable denominated in foreign currencies by using forward foreign exchange contracts and currency option contracts. Refer to "Hedge accounting" in Note 2 "Summary of Significant Accounting Policies" for information on hedge accounting such as hedging instruments, hedged items, hedging policy, evaluation method of effectiveness of hedging activities and so forth.

(c) Risk management for financial instruments

(i) Monitoring of credit risk (the risk that customers or counterparties may default)

In accordance with the procedures determined in the Company, the Accounting and Finance Department and related sections of the Company periodically monitor the conditions of major customers, manage collection due dates and balances of each customer and try to identify credit risk of customers with worsening financial conditions at the early stage and mitigate the risk. Consolidated subsidiaries perform the similar credit management in accordance with the internal rules of the Company.

The Company enters into derivative transactions with financial institutions with high credit ratings to mitigate the counterparty risk.

The maximum amount of credit risk at balance sheet date is represented as the carrying value of financial assets exposed to the credit risk.

(ii) Monitoring of market risks (the risks arising from fluctuations in foreign exchange rates, interest rates and others)

The Company utilizes forward foreign currency exchange contracts and currency option contracts for hedging to mitigate fluctuation risk identified by each foreign currency of trade receivables, payables, forecasted transactions and intercompany loans receivable.

The Company continuously reviews securities holdings by monitoring periodically the market and financial condition of the securities' issuers (companies with business relationships with the Group) and also reviews holding conditions for securities other than held-to-maturities by evaluating the relationship of those companies.

The Accounting and Finance Department enters into derivative transactions under the rules determined in the Company and utilizes forward foreign exchange contracts and currency option contracts within the normal range of transactions. The Accounting and Finance Department manages information on transactions by reporting periodically to the Board of Directors' meetings. Consolidated subsidiaries do not utilize derivative transactions.

(iii) Monitoring of liquidity risk (the risk that the Group may not be able to meet its obligations on scheduled due dates)

The Company manages liquidity risk with the Accounting and Finance Department preparing and updating cash flow plans on a timely basis and keeping necessary funds based on the reports prepared by each department.

(d) Supplementary explanation of the estimated fair value of financial instruments

The fair value of financial instruments is based on their quoted market price, if available. When there is no quoted market price available, fair value is reasonably estimated. Since various assumptions and factors are reflected in estimating the fair value, different assumptions and factors could result in different fair value.

In addition, the notional amounts of derivatives in Note 13 "Derivative Transactions" are not necessarily indicative of the actual market risk involved in the derivative transactions.

(e) Concentration of credit risk

At March 31, 2019 and 2018, 71% and 48%, respectively, of outstanding trade receivables represented receivables due from a specific and large-scale customer.

(2) Fair value of financial instruments

The carrying value of financial instruments on the consolidated balance sheets, fair value and the difference as of March 31, 2019 and 2018, are shown in the following table. The following table does not include financial instruments for which it is extremely difficult to determine the fair value (Please refer to Note 2 below).

	Millions of yen		
	2019		
	Carrying value	Fair value	Difference
Cash and cash equivalents	¥195,801	¥195,801	¥ —
Notes and accounts receivable—trade and affiliates	66,116	66,116	—
Short-term investments and investments in securities	213,492	213,668	176
Total assets	¥475,409	¥475,585	¥176
Notes and accounts payable—trade and affiliates	¥ 9,443	¥ 9,443	¥ —
Current portion of long-term debts:			
Bonds	921	1,535	614
Accrued income taxes	33,157	33,157	—
Total liabilities	¥ 43,521	¥ 44,135	¥614
Derivative transactions (*)	1,077	1,077	—

*Assets and liabilities arising from derivative transactions are shown at net value with the amount in parentheses representing net liability position.

	Millions of yen		
	2018		
	Carrying value	Fair value	Difference
Cash and cash equivalents	¥172,401	¥172,401	¥ —
Notes and accounts receivable—trade and affiliates	53,529	53,529	—
Short-term investments and investments in securities	185,712	185,712	—
Total assets	¥411,642	¥411,642	¥ —
Notes and accounts payable—trade and affiliates	¥ 8,017	¥ 8,017	¥ —
Current portion of long-term debts:			
Long-term loans	10,000	10,123	123
Accrued income taxes	18,337	18,337	—
Long-term debts:			
Bonds	18,492	24,709	6,217
Total liabilities	¥ 54,846	¥ 61,186	¥6,340
Derivative transactions (*)	1,660	1,660	—

*Assets and liabilities arising from derivative transactions are shown at net value with the amount in parentheses representing net liability position.

	Thousands of U.S. dollars		
	2019		
	Carrying value	Fair value	Difference
Cash and cash equivalents	$1,763,973	$1,763,973	$ —
Notes and accounts receivable—trade and affiliates	595,640	595,640	—
Short-term investments and investments in securities	1,923,351	1,924,937	1,586
Total assets	$4,282,964	$4,284,550	$1,586
Notes and accounts payable—trade and affiliates	$ 85,072	$ 85,072	$ —
Current portion of long-term debts:			
Bonds	8,297	13,829	5,532
Accrued income taxes	298,712	298,712	—
Total liabilities	$ 392,081	$ 397,613	$5,532
Derivative transactions (*)	9,703	9,703	—

*Assets and liabilities arising from derivative transactions are shown at net value with the amount in parentheses representing net liability position.

Note 1: Methods to determine the fair value of financial instruments and other matters related to securities and derivative transactions

Assets

- Cash and cash equivalents
  Since these items are settled in a short time period, their carrying value approximates fair value.

- Notes and accounts receivable—trade and affiliates
  Since notes and accounts receivable are settled in a short time period, their carrying value approximates fair value.

- Short-term investments and investments in securities
  With regard to short-term investments and investments in securities, fair value of debt securities is mainly determined by quoted market price or price offered by financial institutions and that of equity securities is determined by quoted market price. Refer to Note 5 "Short-Term Investments and Investments in Securities" for the information of securities by holding purpose.
  However, the carrying value of money in trust for cash management included in short-term investments approximates fair value, because these items are settled in a short time period.

Liabilities

- Notes and accounts payable—trade and affiliates and accrued income taxes
  Since these items are settled in a short time period, their carrying value approximates fair value.

- Current portion of long-term debts
  The fair value of bonds is determined by quoted price offered by financial institutions.
  The fair value of long-term loans is based on the present value of the total of principal and interest discounted by the estimated interest rates to be applied if similar new loans are made.

- Derivative transactions
  Please refer to Note 13 "Derivative Transactions" of these notes to the consolidated financial statements.

Note 2: Financial instruments for which it is extremely difficult to determine the fair value

	Millions of yen		Thousands of U.S. dollars
	2019	2018	2019
Unlisted equity securities	¥62,289	¥60,627	$561,162

Because no quoted market price is available and it is extremely difficult to determine the fair value, the above financial instruments are not included in the preceding table.

Note 3: The redemption schedule for monetary assets and marketable securities with maturities at March 31, 2019 and 2018

	Millions of yen			
	2019			
	Due in 1 year or less	Due after 1 year through 5 years	Due after 5 years through 10 years	Due after 10 years
Cash and cash equivalents	¥195,796	¥ —	¥ —	¥ —
Notes and accounts receivable—trade and affiliates	66,116	—	—	—
Short-term investments and investments in securities:				
Government bonds, municipal bonds, etc.	—	14,000	—	2,000
Other securities with maturities	127,248	—	—	—
Total	¥389,160	¥14,000	¥ —	¥2,000

	Millions of yen			
	2018			
	Due in 1 year or less	Due after 1 year through 5 years	Due after 5 years through 10 years	Due after 10 years
Cash and cash equivalents	¥172,396	¥ —	¥ —	¥ —
Notes and accounts receivable—trade and affiliates	53,529	—	—	—
Short-term investments and investments in securities:				
Government bonds, municipal bonds, etc.	—	12,000	2,000	2,000
Other securities with maturities	92,006	1,456	—	—
Total	¥317,931	¥13,456	¥2,000	¥2,000

	Thousands of U.S. dollars			
	2019			
	Due in 1 year or less	Due after 1 year through 5 years	Due after 5 years through 10 years	Due after 10 years
Cash and cash equivalents	$1,763,928	$ —	$ —	$ —
Notes and accounts receivable—trade and affiliates	595,640	—	—	—
Short-term investments and investments in securities:				
Government bonds, municipal bonds, etc.	—	126,126	—	18,018
Other securities with maturities	1,146,378	—	—	—
Total	$3,505,946	$126,126	$ —	$18,018

13. Derivative Transactions

(1) Derivative transactions to which hedge accounting is not applied

Currency-related transactions

There were no currency-related derivative transactions to which hedge accounting is not applied for the year ended March 31, 2019.

		Millions of yen			
		2018			
		Contract value			
Classification	Transaction	Notional amount	Portion of notional amount over 1 year	Estimated fair value	Unrealized loss
Over-the-counter transaction	Forward foreign currency exchange contracts				
	Selling: USD	¥42,500	¥—	¥(32)	¥(32)

Note: Fair values are calculated based on the prices provided by counterparty financial institutions.

(2) Derivative transactions to which hedge accounting is applied

Currency-related transactions

			Millions of yen		
			2019		
			Contract value		
Method of hedge accounting	Transaction	Major hedged item	Notional amount	Portion of notional amount over 1 year	Fair value
Allocation method	Forward foreign currency exchange contracts				
	Selling: GBP	Forecasted transactions	¥ 98,614	¥ —	¥1,049
	Subtotal		98,614	—	1,049
Deferral hedge	Forward foreign currency exchange contracts				
	Selling: USD	Forecasted transactions	11,100	—	(0)
	Buying: USD	Forecasted transactions	8,436	—	29
	Currency options				
	Buying call options: USD	Forecasted transactions	2,664	—	5
	Selling put options: USD	Forecasted transactions	2,664	—	(6)
	Subtotal		24,864	—	28
	Total		¥123,478	¥ —	¥1,077

			Millions of yen		
			2018		
			Contract value		
Method of hedge accounting	Transaction	Major hedged item	Notional amount	Portion of notional amount over 1 year	Fair value
Allocation method	Forward foreign currency exchange contracts				
	Selling: GBP	Forecasted transactions	¥101,969	¥ —	¥1,693
	Total		¥101,969	¥ —	¥1,693

			Thousands of U.S. dollars		
			2019		
			Contract value		
Method of hedge accounting	Transaction	Major hedged item	Notional amount	Portion of notional amount over 1 year	Fair value
Allocation method	Forward foreign currency exchange contracts				
	Selling: GBP	Forecasted transactions	$ 888,414	$ —	$9,450
	Subtotal		888,414	—	9,450
Deferral hedge	Forward foreign currency exchange contracts				
	Selling: USD	Forecasted transactions	100,000	—	(0)
	Buying: USD	Forecasted transactions	76,000	—	261
	Currency options				
	Buying call options: USD	Forecasted transactions	24,000	—	45
	Selling put options: USD	Forecasted transactions	24,000	—	(54)
	Subtotal		224,000	—	252
	Total		$1,112,414	$ —	$9,703

Notes: 1. Fair values are calculated based on the prices provided by counterparty financial institutions.
2. The currency option transactions are zero-cost options and no premium is received or paid.

14. Shareholders' Equity

The Company Act of Japan (the "Act") provides that an amount equal to 10% of the amount to be disbursed as distributions of capital surplus (other than the capital reserve) and retained earnings (other than the legal reserve) be transferred to the capital reserve and the legal reserve, respectively, until the sum of the capital reserve and the legal reserve equals 25% of the capital stock account. Such distributions can be made at any time by resolution of the shareholders, or by the Board of Directors if certain conditions are met.

The Company's legal reserve included in retained earnings at March 31, 2019 and 2018 amounted to ¥5,388 million ($48,541 thousand), respectively.

Under the Act, upon the issuance and sale of new shares of common stock, the entire amount of the proceeds is required to be accounted for as common stock, although a company may, by resolution of the Board of Directors, account for an amount not exceeding one-half of the proceeds of the sale of new shares as additional paid-in capital included in capital surplus.

Movements in issued shares of common stock and treasury stock during the years ended March 31, 2019 and 2018 are summarized as follows:

	Number of shares			
	2019			
	April 1, 2018	Increase	Decrease	March 31, 2019
Issued shares of common stock	324,136,165	—	7,350,000	316,786,165
Treasury stock	9,780,027	7,353,561	11,634,837	5,498,751

	Number of shares			
	2018			
	April 1, 2017	Increase	Decrease	March 31, 2018
Issued shares of common stock	329,136,165	—	5,000,000	324,136,165
Treasury stock	10,347,876	4,803,153	5,371,002	9,780,027

The decrease in the number of shares of common stock during the year ended March 31, 2019 is due to the retirement of treasury stock.

The increase in the number of shares of treasury stock during the year ended March 31, 2019 consists of 7,350,400 shares due to the purchase of treasury stock based on resolution of the Board of Directors and 3,161 shares due to the purchase of fractional shares of less than one voting unit.

The decrease in the number of shares of treasury stock during the year ended March 31, 2019 consists of 7,350,000 shares due to the retirement of treasury stock and 4,249,737 shares due to the conversion of convertible bonds with share subscription rights and 35,100 shares due to the grants under the restricted stock compensation plans.

The decrease in the number of shares of common stock during the year ended March 31, 2018 is due to the retirement of treasury stock.

The increase in the number of shares of treasury stock during the year ended March 31, 2018 consists of 4,800,000 shares due to the purchase of treasury stock based on resolution of the Board of Directors and 3,153 shares due to the purchase of fractional shares of less than one voting unit.

The decrease in the number of shares of treasury stock during the year ended March 31, 2018 consists of 5,000,000 shares due to the retirement of treasury stock and 371,002 shares due to the exercise of share subscription rights.

Stock Options

The Company has a stock option plan for its directors and corporate officers. Stock option expense included in selling, general and administrative expenses amounted to ¥12 million ($108 thousand) and ¥110 million for the years ended March 31, 2019 and 2018, respectively.

A stock option plan for three directors and twelve corporate officers of the Company was approved at the annual general meeting of the shareholders of the Company held on June 22, 2017 ("the 2017 plan"). Under the terms of this plan, 19,300 shares of common stock were granted and vested immediately. The options became exercisable on July 8, 2017 and are scheduled to expire on July 7, 2047.

A stock option plan for three directors and ten corporate officers of the Company was approved at the annual general meeting of the shareholders of the Company held on June 23, 2016 ("the 2016 plan"). Under the terms of this plan, 17,300 shares of common stock were granted and vested immediately. The options became exercisable on July 9, 2016 and are scheduled to expire on July 8, 2046.

A stock option plan for three directors and eleven corporate officers of the Company was approved at the annual general meeting of the shareholders of the Company held on June 24, 2015 ("the 2015 plan"). Under the terms of this plan, 21,100 shares of common stock were granted and vested immediately. The options became exercisable on July 10, 2015 and are scheduled to expire on July 9, 2045.

A stock option plan for two directors and eleven corporate officers of the Company was approved at the annual general meeting of the shareholders of the Company held on June 26, 2014 ("the 2014 plan"). Under the terms of this plan, 42,400 shares of common stock were granted and vested immediately. The options became exercisable on July 11, 2014 and are scheduled to expire on July 10, 2044.

A stock option plan for two directors and twelve corporate officers of the Company was approved at the annual general meeting of the shareholders of the Company held on June 26, 2013 ("the 2013 plan"). Under the terms of this plan, 43,900 shares of common stock were granted and vested immediately. The options became exercisable on July 12, 2013 and are scheduled to expire on July 11, 2043.

A stock option plan for two directors and eleven corporate officers of the Company was approved at the annual general meeting of the shareholders of the Company held on June 27, 2012 ("the 2012 plan"). Under the terms of this plan, 79,100 shares of common stock were granted and vested immediately. The options became exercisable on July 13, 2012 and are scheduled to expire on July 12, 2042.

A stock option plan for three directors and nine corporate officers of the Company was approved at the annual general meeting of the shareholders of the Company held on June 24, 2011 ("the 2011 plan"). Under the terms of this plan, 52,200 shares of common stock were granted and vested immediately. The options became exercisable on July 12, 2011 and are scheduled to expire on July 11, 2041.

Movement in the number of stock options after vesting for the 2011, 2012, 2013, 2014, 2015, 2016 and 2017 plans of the Company during the year ended March 31, 2019 is summarized as follows:

	2017 plan	2016 plan	2015 plan	2014 plan	2013 plan	2012 plan	2011 plan
	(Number of options)						
Outstanding as of April 1, 2018	19,300	17,300	20,200	36,300	33,800	63,300	36,800
Vested	—	—	—	—	—	—	—
Exercised	—	—	—	—	—	—	—
Forfeited	—	—	—	—	—	—	—
Outstanding as of March 31, 2019	19,300	17,300	20,200	36,300	33,800	63,300	36,800

The unit price of the stock options after vesting under the 2011, 2012, 2013, 2014, 2015, 2016 and 2017 plans of the Company as of March 31, 2019 is summarized as follows:

	2017 plan		2016 plan		2015 plan		2014 plan	
	Yen	U.S. dollars	Yen	U.S. dollars	Yen	U.S. dollars	Yen	U.S. dollars
Unit price of stock options:								
Exercise price as of March 31, 2019	¥ 1	$ 0.01	¥ 1	$ 0.01	¥ 1	$ 0.01	¥ 1	$ 0.01
Average market price per share upon exercise	—	—	—	—	—	—	—	—
Estimated fair value of unit price at grant date	5,741	51.72	5,256	47.35	4,553	41.02	1,899	17.11

	2013 plan		2012 plan		2011 plan	
	Yen	U.S. dollars	Yen	U.S. dollars	Yen	U.S. dollars
Unit price of stock options:						
Exercise price as of March 31, 2019	¥ 1	$ 0.01	¥ 1	$0.01	¥ 1	$ 0.01
Average market price per share upon exercise	—	—	—	—	—	—
Estimated fair value of unit price at grant date	1,930	17.39	916	8.25	1,129	10.17

Because it is difficult to reasonably estimate the number of stock options that will be forfeited, the estimation reflects only the actual number of forfeited stock options.

15. Supplementary Information on Consolidated Statement of Income

(Reversal of provision) provision for sales returns

(Reversal of provision) provision for sales returns included in net sales and cost of sales for the years ended March 31, 2019 and 2018 amounted to ¥68 million ($613 thousand) and ¥(206) million, respectively.

Research and development expenses

Research and development expenses included in selling, general and administrative expenses for the years ended March 31, 2019 and 2018 amounted to ¥68,325 million ($615,541 thousand) and ¥59,946 million, respectively.

Gain on sales of property, plant and equipment

Gain on sales of property, plant and equipment for the year ended March 31, 2019 mainly includes a gain of ¥2,406 million ($21,676 thousand) recognized by C&O Pharmaceutical Technology (Holdings) Ltd., the Company's subsidiary, as a result of selling the Nanjing plant in China and a gain of ¥451 million ($4,063 thousand) recognized by the Company as a result of selling the Omori Dormitory for employees in Tokyo, Japan.

Special retirement expenses

Special retirement expenses for the year ended March 31, 2019 are retirement expenses in the amounts of ¥2,504 million ($22,559 thousand) and ¥345 million ($3,108 thousand) recognized by the Company and Netherlands subsidiary, Shionogi B.V.

The former represent payments related to the transfer system from the Company to Shionogi Pharma Co., Ltd. of the Company's subsidiary.

Loss on disaster

For the year ended March 31, 2019, the Company recorded loss on disaster in connection with the impact of an earthquake that occurred in northern Osaka on June 18, 2018.

16. Other Comprehensive (Loss) Income

The following table presents the analysis of other comprehensive (loss) income for the years ended March 31, 2019 and 2018.

	Millions of yen		Thousands of U.S. dollars
	2019	2018	2019
Net unrealized holding (loss) gain on securities:			
Amount arising during the year	¥ 8,352	¥13,473	$ 75,244
Reclassification adjustments included in gains or losses	(17,943)	796	(161,649)
Before tax effect	(9,591)	14,269	(86,405)
Tax effect	2,662	(3,454)	23,982
Total	(6,929)	10,815	(62,423)
Deferred (loss) gain on hedges:			
Amount arising during the year	(728)	1,677	(6,559)
Reclassification adjustments included in gains or losses	113	(161)	1,018
Before tax effect	(615)	1,516	(5,541)
Tax effect	188	(464)	1,694
Total	(427)	1,052	(3,847)
Translation adjustments:			
Amount arising during the year	(3,261)	4,766	(29,378)
Reclassification adjustments included in gains or losses	—	—	—
Before tax effect	(3,261)	4,766	(29,378)
Tax effect	—	—	—
Total	(3,261)	4,766	(29,378)
Retirement benefit liability adjustments:			
Amount arising during the year	3,337	3,048	30,063
Reclassification adjustments included in gains or losses	2,336	4,375	21,045
Before tax effect	5,673	7,423	51,108
Tax effect	(1,736)	(2,272)	(15,640)
Total	3,937	5,151	35,468
Other comprehensive (loss) income	¥ (6,680)	¥21,784	$ (60,180)

17. Related Party Transactions

Related party transactions for the years ended March 31, 2019 and 2018 and the related balances at March 31, 2019 and 2018 are summarized as follows:

Principal transactions between consolidated subsidiaries and related parties

	Millions of yen		Thousands of U.S. dollars
	2019	2018	2019
Shunjusha Co., Ltd.:			
Rent received—land and office building	¥ 52	¥ 52	$ 468
Rent expense—building	148	148	1,333
Management fee for leased property	4	4	36
Lease deposits, a component of other assets	42	42	378
Long-term lease deposits received, a component of other long-term liabilities	1	1	9

Shunjusha Co., Ltd. is directly owned by a director and a relative of the director of the Company and is engaged in the real estate leasing business. The percentage of voting rights owned by these two people was 100% as of March 31, 2019 and 2018. Shunjusha Co., Ltd. is located in Chuo-ku, Osaka with a capital amount of ¥100 million ($901 thousand) at March 31, 2019 and 2018, respectively.

The prices for the above related party transactions were determined with reference to market value, transactions made in the same area and so on.

18. Amounts per Share

Amounts per share as of and for the years ended March 31, 2019 and 2018 were as follows:

	Yen		U.S. dollars
	2019	2018	2019
Profit attributable to owners of parent:			
Basic	¥ 424.31	¥ 342.71	$ 3.82
Diluted	420.67	337.43	3.79
Net assets	2,144.33	1,911.36	19.32
Cash dividends applicable to the year	94.00	82.00	0.85

Basic profit attributable to owners of parent per share is computed based on the profit attributable to owners of parent available for distribution to shareholders of common stock and the weighted-average number of shares of common stock outstanding during the year. Diluted profit attributable to owners of parent per share is computed based on the profit attributable to owners of parent available for distribution to shareholders and the weighted-average number of shares of common stock outstanding during each year after giving effect to the dilutive potential of shares of common stock to be issued upon the exercise of stock options and stock subscription rights.

Net assets per share have been computed based on the net assets excluding share subscription rights and non-controlling interests and the number of shares of common stock outstanding at the year end.

Cash dividends per share represent the cash dividends proposed by the Board of Directors as applicable to the respective years together with the interim cash dividends paid.

The financial data used in the computation of profit per share and diluted profit per share for the years ended March 31, 2019 and 2018 in the table above is summarized as follows:

	Millions of yen		Thousands of U.S. dollars
	2019	2018	2019
Profit attributable to owners of parent	¥132,759	¥108,867	$1,196,027
Adjustments to profit attributable to owners of parent:			
Interest income, net of tax	(7)	(14)	(63)

	Thousands of shares	
	2019	2018
Weighted-average number of shares of common stock outstanding	312,883	317,660
Increase in common stock:		
Bonds	2,465	4,713
Share subscription rights	227	222
Total	2,692	4,935

The financial data used in the computation of net assets per share at March 31, 2019 and 2018 in the above table is summarized as follows:

	Millions of yen		Thousands of U.S. dollars
	2019	2018	2019
Total net assets	¥672,430	¥604,841	$6,057,928
Amounts deducted from total net assets:			
Amounts attributable to share subscription rights in total net assets	(528)	(528)	(4,757)
Amounts attributable to non-controlling interests in total net assets	(4,400)	(3,466)	(39,640)
Net assets used in the computation of net assets per share	¥667,502	¥600,847	$6,013,531

	Thousands of shares	
	2019	2018
Number of shares used in the computation of net assets per share	311,287	314,356

19. Segment Information

1. Segment information for the years ended March 31, 2019 and 2018

The Group operates as a single business segment related to prescription drugs involving research and development, purchasing, manufacturing, distribution and related businesses for prescription drugs. While analyses of sales by products and evaluation of performance by group companies is performed, decisions of business strategy and allocation of management resources, especially allocation of research and development expenses, are made on a Group-wide basis. Therefore, disclosure of segment information for the years ended March 31, 2019 and 2018 was omitted.

2. Related information

(1) Information on sales by product and service

As the amount of sales to the third parties of only one type of product and service in a single segment accounted for more than 90% of net sales in the consolidated statement of income for the years ended March 31, 2019 and 2018, information on sales by product and service was omitted.

(2) Geographical information

(a) Net sales

	Millions of yen		Thousands of U.S. dollars
	2019	2018	2019
Japan	¥ 147,131	¥ 159,490	$ 1,325,505
Europe	186,505	160,705	1,680,225
(United Kingdom)	(153,912)	(141,200)	(1,386,595)
North America	13,212	12,360	119,027
(United States of America)	(13,205)	(12,356)	(118,964)
Other	16,874	12,112	152,018
Total	¥ 363,722	¥ 344,667	$ 3,276,775

Net sales information above is classified by countries and/or regions based on locations of customers. The main countries and regions included in each category are as follows:

(1) Europe: United Kingdom, Switzerland, Germany and others
(2) North America: United States of America and others
(3) Other: Asia and others

(b) Property, plant and equipment

As the balances of property, plant and equipment located in Japan accounted for more than 90% of the balances of property, plant and equipment recognized in the consolidated balance sheets at March 31, 2019 and 2018, information on property, plant and equipment by geographical segment was omitted.

(3) Information by major customer

	Net sales			
	Millions of yen		Thousands of U.S. dollars	
Customer name	2019	2018	2019	Related segment name
ViiV Healthcare UK Limited.	¥124,430	¥103,877	$1,120,991	Pharmaceuticals
SUZUKEN CO., LTD.	37,899	47,120	341,432	Pharmaceuticals

3. Information on loss on impairment of fixed assets by reportable segment

The Group operates as a single business segment related to prescription drugs involving research and development, purchasing, manufacturing, distribution and related businesses for prescription drugs. Accordingly, this information for the years ended March 31, 2019 and 2018 was omitted.

4. Information on amortization of goodwill and remaining unamortized balance by reportable segment

As described in the above 3, the Group operates as a single business segment. Accordingly, information on amortization of goodwill and remaining unamortized balance by reportable segment at March 31, 2019 and 2018 and for the years then ended was omitted.

5. Information on gain on negative goodwill by reportable segment

Information on gain on negative goodwill was omitted since there are no items to be disclosed for the years ended March 31, 2019 and 2018.

20. Subsequent Events

(1) Significant absorption-type company split

Based on an absorption-type split agreement approved by resolution of the Board of Directors on February 18, 2019, the Company carried out the following absorption-type split (hereinafter, the "Split") on April 1, 2019.

(a) Purpose of the Split

Shionogi Pharma Co., Ltd. (hereinafter, "Shionogi Pharma"), a wholly owned subsidiary of the Company that was established on October 1, 2018, succeeded the Company's pharmaceutical manufacturing operations for the purpose of providing stable supplies of products with high quality and at competitive prices to domestic and overseas markets, with the Company responsible for the Group's production-related functions and making innovative developments in production technology.

(b) Description of business subject to the Split and book values of assets and liabilities spun off

Description of business:	Manufacturing and contract manufacturing of pharmaceutical products
Assets spun off:	¥50,960 million ($459,099 thousand)
Liabilities spun off:	¥43 million ($387 thousand)

(c) Form of the Split

Simplified absorption-type split with the Company as the splitting company and Shionogi Pharma as the successor company

(d) Name of successor company in the Split, and amounts of its assets, liabilities and net assets (as of March 31, 2019)

Company name:	Shionogi Pharma Co., Ltd.
Assets:	¥25 million ($225 thousand)
Liabilities:	¥165 million ($1,486 thousand)
Net assets:	¥(140) million ($(1,261) thousand)
Note:	Shionogi Pharma commenced operations on April 1, 2019.

(e) Timing of the Split

April 1, 2019

(f) Summary of accounting treatment

The transaction is treated as a transaction under common control based on the Accounting Standard for Business Combinations (ASBJ Statement No.21) and the Implementation Guidance on Accounting Standard for Business Combinations and Accounting Standard for Business Divestitures (ASBJ Guidance No.10).

(g) Other significant items

On the same date, Shionogi Pharma, the successor company, carried out an absorption-type merger involving Shionogi Pharma Chemicals Co., Ltd. and Shionogi Analysis Center Co., Ltd., which were wholly owned subsidiaries of the Company.

(2) Cash dividends

The following distribution of retained earnings of the Company, which has not been reflected in the accompanying consolidated financial statements for the year ended March 31, 2019, was approved at a shareholders' meeting held on June 18, 2019:

	Millions of yen	Thousands of U.S. dollars
Cash dividends (¥50.00 = U.S.$0.45 per share)	¥15,564	$140,216

Independent Auditor's Report

The Board of Directors
Shionogi & Co., Ltd.

We have audited the accompanying consolidated financial statements of Shionogi & Co., Ltd. and its consolidated subsidiaries, which comprise the consolidated balance sheet as at March 31, 2019, and the consolidated statements of income, comprehensive income, changes in net assets, 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 Consolidated Financial Statements

Management is responsible for the preparation and fair presentation of these consolidated financial statements in accordance with accounting principles generally accepted in Japan, and for designing and operating such internal control as management determines is necessary to enable the preparation and fair presentation of the consolidated 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 consolidated 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 consolidated financial statements are free from material misstatement.

An audit involves performing procedures to obtain audit evidence about the amounts and disclosures in the consolidated financial statements. The procedures selected depend on the auditor's judgment, including the assessment of the risks of material misstatement of the consolidated financial statements, whether due to fraud or error. The purpose of an audit of the consolidated financial statements is not to express an opinion on the effectiveness of the entity's internal control, but in making these risk assessments the auditor considers internal controls relevant to the entity's preparation and fair presentation of the consolidated financial statements in order to design audit procedures that are appropriate in the circumstances. 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 consolidated 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 consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of Shionogi & Co., Ltd. and its consolidated subsidiaries as at March 31, 2019, and their consolidated financial performance and cash flows for the year then ended in conformity with accounting principles generally accepted in Japan.

Convenience Translation

We have reviewed the translation of these consolidated financial statements into U.S. dollars, presented for the convenience of readers, and, in our opinion, the accompanying consolidated financial statements have been properly translated on the basis described in Note 4.

June 17, 2019
Osaka, Japan

Ernst & Young ShinNihon LLC

Our history

One hundred and forty-one years now have passed since Shiono Gisaburo Shoten, the drug wholesaler that would become Shionogi & Co., Ltd., began operations in Doshomachi, Osaka, in 1878.
Since then, Shionogi has evolved into a leading pharmaceutical manufacturer via the development of our first proprietary antibiotic, *Shinomin*; the launch of *Shiomarin*, the world's first oxacephem antibiotic, also developed in-house; and the success of our hyperlipidemia treatment *Crestor*, which has grown into a blockbuster.
From fiscal 2005, the Company identified priority therapeutic areas, concentrating business resources on infectious diseases, pain treatment, and metabolic diseases.
From fiscal 2010, we launched the anti-HIV agent *Tivicay* and other new growth drivers as we succeeded in our transition to a more robust profit-generating business structure. We aim to achieve further transformation by continuing to address healthcare needs.

1850–

1878
Company founded
- Gisaburo Shiono, Sr., founder of the Company, launched Shiono Gisaburo Shoten as a drug wholesaler at the present site of the head office, Doshomachi, Osaka.

Founder Gisaburo Shiono, Sr.
(1854-1931)
Gisaburo Shiono, Sr. was born in 1854 in Doshomachi, Osaka. He learned the wholesale trade under the guidance of his father Kichibe, and launched his own drug wholesaling business in Doshomachi on his 24th birthday, on March 17, 1878. This wholesaler was the predecessor of Shionogi & Co., Ltd.

1886
From Japanese medicine to Western medicine
- Shionogi switches its focus to imported Western drugs.

1897
- Shionogi starts to deal directly with trading firms in Europe and the US.

1900–

1909
From Western medicine to new drugs
- ***Antacidin*, an antacid agent, was launched as the first drug produced.**
- Registered the corporate emblem FUNDOH.

(FUNDOH from the Edo era)

Shionogi's corporate emblem

1910
- Constructed the Shiono Seiyakusho manufacturing plant.
  The seeds of our current SGS2020 vision – Grow as a drug discovery-based pharmaceutical company.

1919
- Shiono Gisaburo Shoten and Shiono Seiyakusho were merged and the new company was named Shionogi Shoten Co., Ltd.

1922
- Constructed the Kuise Plant (now the Kuise office).

1924
- Constructed new head office in Doshomachi, Osaka (rebuilt in 1993).

1943
- Renamed the Company Shionogi Seiyaku K.K. (now Shionogi & Co., Ltd.).

1946
- Developed the Aburahi Laboratories (now the Aburahi Facilities).
  Initiative launched to protect endangered plant species and rare plants.

1947
- Formation of Shionogi Seiyaku's women's softball team

1950–

1954
- Established the Hoansha Foundation to provide economic support to individuals and businesses involved in pharmaceutical research.

1957
The Company Policy of Shionogi was established.

1959
- **Launched sulfonamide drug *Shinomin*.**

1963
- Established Taiwan Shionogi & Co., Ltd.

1964
- First episode of Shionogi Music Fair, a TV music program sponsored exclusively by Shionogi.

1968
- Established the Settsu Plant.

1980
- Established the Developmental Research Laboratories (now Shionogi Pharmaceutical Research Center (SPRC)).

1982
- **Launched oxacephem antibiotic *Shiomarin*.**

1983
- Constructed the Kanegasaki Plant.

1988
- **Launched oxacephem antibiotic *Flumarin*.**
- Established the Cell Science Research Foundation to promote cell science research and encourage more researchers to work in the field.

1997
- **Launched cephem antibiotic *Flomox*.**

1998
- Established the Shionogi Charter of Conduct (revised 2012).

2000–

2000– The First Medium-Term Business Plan

Completion of corporate restructuring to concentrate on pharmaceutical business.

Transferred or sold six businesses: drug wholesaling, agrochemical, clinical laboratory, animal health products, industrial chemicals and capsules.

2001
- Established Shionogi USA, Inc. (now Shionogi Inc.).
- Established joint venture Shionogi-GlaxoSmithKline Pharmaceuticals LLC (now Shionogi-ViiV Healthcare LLC). Started joint R&D into HIV drugs.

2003
- **Launched cancer pain analgesic *OxyContin*** (followed by powdered version *OxiNorm* in 2007, injectable version *OxiFast* in 2012).

2005– The Second Medium-Term Business Plan

Established a constant flow of pipeline products through energizing and globalizing R&D.

2005
- **Launched hyperlipidemia treatment *Crestor*.**
- **Launched carbapenem antibiotic *Finibax*.**

2008
- **Launched hypertension treatment *Irbetan*** (followed by combination drug *AIMIX* in 2012, combination drug *IRTRA* in 2013).
- Established the Shionogi Innovation Center for Drug Discovery, a joint research facility with Hokkaido University.
- Acquired Sciele Pharma, Inc. (now Shionogi Inc.).
- **Launched idiopathic pulmonary fibrosis treatment *Pirespa*.**

2010– The Third Medium-Term Business Plan

Launch of multiple products developed globally and real growth.

2010
- **Launched flu drug *Rapiacta*.**
- **Launched SNRI *Cymbalta*.**
- Established the PET Molecular Imaging Center at the Osaka University Graduate School of Medicine.
- Established Shionogi Inc. (Florham Park, New Jersey) as the US group headquarters.
- Established Shionogi Techno Advance Research Co., Ltd.

2011
- Established the Shionogi Pharmaceutical Research Center (SPRC4). Drug discovery research functions consolidated at SPRC.

- Acquired C&O Pharmaceutical Technology (Holdings) Limited, a Chinese pharmaceutical company.

2012
- Established European subsidiary Shionogi Limited (London, UK).

2013
- Established Shionogi Pharmaceutical Technology Limited (Beijing) as a China subsidiary.
- **Launched postmenopausal vulvar and vaginal atrophy treatment *Osphena* in the US.**
- Established Shionogi Singapore Pte. Ltd. as a Singapore subsidiary.

2014– New Medium-Term Business Plan

Shionogi Growth Strategy 2020

Grow as a drug discovery-based pharmaceutical company.

2014
- **Launched HIV treatment *Tivicay*.**

2015
- **Launched anti-HIV agent *Triumeq*.**
- **Launched allergen immunotherapy *Actair*.**
- **Launched thrombocytopenia treatment *Mulpleta*.**

2016– New Medium-Term Business Plan Update to Shionogi Growth Strategy 2020 (SGS2020)

Grow sustainably as a drug discovery-based pharmaceutical company contributing to a more vigorous society through improved healthcare
- Established Shionogi Healthcare Co., Ltd.
- **Launched hyperlipidemia treatment *Crestor* OD tablets.**

2017
- **Launched cancer pain treatment *Methapain*.**
- **Launched ADHD therapeutic agent *Intuniv*.**
- **Launched opioid-induced constipation (OIC) treatment *Symproic*.**
- **Launched chronic cancer pain treatment *OxyContin* TR tablets.**
- Established Shionogi Marketing Solutions Co., Ltd.
- Established Shionogi Pharmacovigilance Center Co., Ltd.
- Established Shionogi Business Partner Co., Ltd.
- Established Shionogi Digital Science Co., Ltd.
- Established Shionogi Administration Service Co., Ltd.
- Established Shionogi Career Development Center Co., Ltd.

2018
- **Launched flu drug *Xofluza*.**
- **Launched thrombocytopenia treatment *Mulpleta* in the US.**
- **Launched anti-HIV agent *Juluca*.**
- Established Shionogi Pharma Co., Ltd.
- Established European subsidiary Shionogi B.V.

Non-financial data

	Mar. 31, 2015	Mar. 31, 2016	Mar. 31, 2017	Mar. 31, 2018	Mar. 31, 2019	Remark
Information on the number of employees (Information about only Shionogi & Co., Ltd. unless otherwise stated)						
No. of employees						
Consolidated	6,059 persons	5,896 persons	5,511 persons	5,120 persons	5,233 persons (4,554 persons)	The figure in parentheses is calculated for domestic consolidated companies.
Shionogi & co., Ltd.	4,139 persons	4,055 persons	3,911 persons	3,677 persons	3,596 persons	
Rate of female employees	28.7%	28.8%	28.8%	27.8%	28.1% (32.2%)	The figure in parentheses is calculated for domestic consolidated companies.
Average age						
Total	41.3 years old	41.4 years old	41.7 years old	41.4 years old	41.7 years old	Excluding seconded persons
Male	41.9 years old	42.1 years old	42.2 years old	41.9 years old	42.2 years old	
Female	39.6 years old	39.8 years old	40.6 years old	40.0 years old	40.4 years old	
Length of service						
Total	17.1 years	17.2 years	17.4 years	17.3 years	17.3 years	Excluding seconded persons
Male	17.0 years	17.1 years	17.1 years	16.9 years	17.1 years	
Female	17.4 years	17.5 years	18.1 years	17.4 years	17.8 years	
Average salary	8,360,225 yen	8,901,271 yen	9,276,750 yen	9,193,748 yen	9,042,130 yen	
No. of new recruits						
Total	98 persons	99 persons	91 persons	110 persons	101 persons	Recruits who will enter the company on April 1 of the following fiscal year
Male	57 persons	57 persons	61 persons	71 persons	59 persons	
Female	41 persons	42 persons	30 persons	39 persons	42 persons	
Turnover rate of recruits enrolled for three years	6.3%	0.0%	6.5%	6.5%	3.0%	Recruit who entered the company on April 1 three years ago
Turnover rate of employees	1.4%	1.4%	1.4%	1.9%	1.6%	Excluding retired persons
No. of labor union members	3,369 persons Rate of union members: 100%	3,396 persons Rate of union members: 100%	2,948 persons Rate of union members: 100%	2,758 persons Rate of union members: 100%	3,012 persons Rate of union members: 100%	
Employment rate of people with disabilities	2.1%	2.1%	2.3%	2.2%	2.0%(2.5%)	As of the end of March. The figure in parentheses is calculated for special cases in affiliated companies. Shionogi Smile Heart Co., Ltd. established in April 2018 and certified as a special subsidiary company in July 2018.
Rate of female managers	7.0%	7.8%	8.4%	8.0%	9.9%(10.0%)	As of April 1 of the following fiscal year.The figure in parentheses is calculated for domestic consolidated companies. Target: 10%(Domestic consolidation at the end of March 2021)
Rate of female heads of organizations	—	5.6%	6.7%	7.7%	8.6%	As of April 1 of the following fiscal year
Rate of female corporate officers	1/12 8.3%	2/13 15.4%	2/12 16.7%	1/14 7.1%	1/13 7.7%	As of April 1 of the following fiscal year
Rate of female members of the Board	0.0%	16.7%	16.7%	16.7%	16.7%	As of April 1 of the following fiscal year
Information on labor management (Shionogi & Co., Ltd.)						
Annual regular working hours for employees	1,860 hours	1,852 hours	1,860 hours	1,860 hours	1,852 hours	
No. of paid holidays	Up to 24 days	Up to 24 days	Up to 24 days	Up to 24 days	Up to 24 days	The number of legal annual holidays based on the Labor Standards Act is up to 20 days.
Average No. of paid holidays taken by employees	14.9 days	13.4 days	13.6 days	12.0 days	12.5 days	
Acquisition rate of childcare leave						
Female	100%	100%	100%	100%	100%	Rate of employees who have taken childcare leave during the year when their baby was born
Male	3.9%	14.8%	17.4%	21.0%	24.2%	
No. of employees who have taken nursing care leave						
Female	1 person	7 persons	4 persons	4 persons	2 persons	Total number
Male	2 persons	0 person	0 person	0 person	0 person	
No. of employees who have worked on short work hours due to child rearing						
Female	174 persons	181 persons	173 persons	162 persons	119 persons	Total number
Male	0 person	4 persons	2 persons	1 person	1 person	
Volunteer leave	2 persons	0 person	0 person	1 person	0 person	From FY 2014
Leave for bone marrow transplant donors	1 person	1 person	1 person	0 person	0 person	From FY 2014
Frequency rate	0.23	0.12	0.25	0.39	0.81	
Severity rate	0.006	0.0001	0.004	0.003	0.018	
Legal violation / Administrative guidance	0 case	0 case	0 case	0 case	4 cases	
Health (Shionogi & Co., Ltd.)						
Smoking rate	20.5%	18.7%	17.1%	16.4%	15.2%	Target: 15% to 16%
Rate of stress check attendance	—	—	94%	94%	96%	Target: 94% or higher
Participation rate in a healthy walk	31.8%	37.1%	35.4%	42.2%	41.5%	Target: 40%
Rate of health checkup attendance	100%	100%	100%	100%	100%	
Rate of employees on leave due to mental disorders	0.7%	0.7%	0.5%	0.4%	0.4%	
Environment (Domestic consolidated companies)						
CO_2 emissions (Scope 1 and 2)	68,194 tons-CO_2	69,420 tons-CO_2	67,764 tons-CO_2	64,370 tons-CO_2	61,866 tons-CO_2	
Energy consumption (Thousand)	1,693GJ	1,697GJ	1,657GJ	1,581GJ	1,522GJ	
Water use (Thousand)	1,583m^3	1,567m^3	1,528m^3	1,389m^3	1,315m^3	
Amount of waste generated	3,509 tons	3,944 tons	3,820 tons	3,486 tons	3,824 tons	
Recycling rate	71%	71%	79%	78%	81%	
Landfill rate	2.0%	2.5%	1.3%	1.0%	0.8%	
Type 1 chemicals designated under the PRTR Act						
Amount used	279 tons	377 tons	289 tons	251 tons	274 tons	
Amount released	50 tons	61 tons	63 tons	35 tons	43 tons	
Amount transferred	170 tons	235 tons	148 tons	177 tons	156 tons	
No. of complaints about the environment	1 case	1 case	1 case	2 cases	1 case	

Corporate information (As of March 31, 2019)

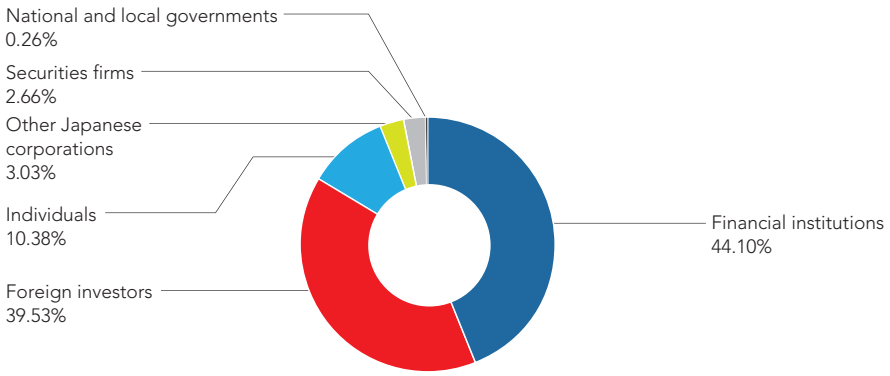
Corporate Data

Company Name	Shionogi & Co., Ltd.
Established	March 17, 1878
Incorporated	June 5, 1919
Paid-in Capital	¥21,280 million
Number of Employees Consolidated	5,233
Fiscal Year-End	March 31
Website	http://www.shionogi.co.jp/en/

Investor Information

Stock (Securities) Listings:	Tokyo (#4507) (Shares listed in 1949)
Common Stock Authorized:	1,000,000,000 shares
Issued:	316,786,165 shares
Number of shareholders:	35,768

Shareholder Composition



Note: Treasury stock included in Individuals

Major Shareholders

Name	Number of shares (Thousands)	Percentage of total shares (%)
The Master Trust Bank of Japan, Ltd. (Trust account)	36,408	11.69
Japan Trustee Services Bank, Ltd. (Trust account)	20,200	6.48
Sumitomo Life Insurance Company	18,604	5.97
SMBC Trust Bank Ltd. (as a trustee for retirement benefit of Sumitomo Mitsui Banking Corporation)	9,485	3.04
Nippon Life Insurance Company	8,409	2.70
STATE STREET BANK AND TRUST COMPANY 505001	5,859	1.88
Japan Trustee Services Bank, Ltd (Trust account 5)	5,017	1.61
Japan Trustee Services Bank, Ltd (Trust account 7)	5,000	1.60
STATE STREETWEST CLIENT-TREATY 505234	4,970	1.59
Sumitomo Mitsui Banking Corporation	4,595	1.47

Notes:
1. The Company owns 5,498,751 shares of treasury stock but the Company is not included in the major shareholders listed above (top 10).
2. The percentage of total is calculated as the proportion of shares to 311,287,414 shares of total issued stock (excluding 5,498,751 shares of treasury stock).

SHIONOGI

S-O-N-G

for you!