

# SHIONOGI GROWTH STRATEGY 2020



### Contents

Strengths that increase our value to society

**Creating long-term value** 

Supporting sustainable manufacturing processes

### **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 2015 (April 1, 2015–March 31, 2016) Certain activities continuing after fiscal 2015 are also included.

#### Scope and Organization

This Integrated Report encompasses the activities of Shionogi & Co., Ltd. and 37 consolidated subsidiaries.

In this report, "Shionogi" refers to Shionogi & Co., Ltd. and all its on-site subsidiaries. "Domestic subsidiaries" refers to the one domestic manufacturing subsidiary (Shionogi Pharma Chemicals Co., Ltd.) and three domestic non-manufacturing subsidiaries (Shionogi General Service Co., Ltd., Saishin Igaku Co., Ltd. and Shionogi Healthcare & Co., Ltd.). "Shionogi Group" refers to all the aforementioned companies.

The section entitled Respecting the Environment covers all business facilities of Shionogi & Co., Ltd., and six 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 production 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 nor provide medical advice of any kind.

# **The Company Policy of Shionogi**

(Established in 1957)

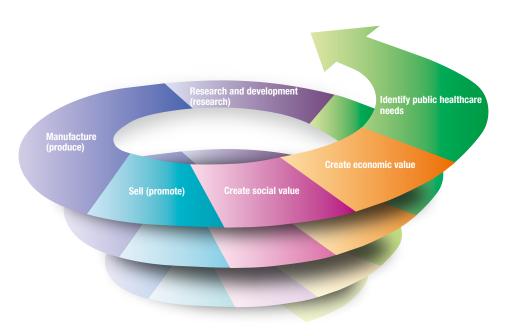
# Shionogi's purpose

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.



We fulfill our responsibilities to society by consistently creating value through our business activities.

# Our Company Policy sits at the heart of value creation at Shionogi

Since Shionogi was established, our corporate culture has been underpinned by a commitment to develop even better medicines and deliver them to patients in need. By constantly improving our technologies and services, we have worked to enhance the positive impact of our products on patient health. This culture and approach has been an unshakeable feature of Shionogi over the years, even as everything around us has changed.

We established the Company Policy of Shionogi in 1957 and it remains the template for the kind of company we want to be and the basis of our value to society. The fundamental tenet of this policy – to protect the health and wellbeing of the people we serve – has always been our guiding principle as a pharmaceutical company. Anchored by this principle, we will continue to deliver and create new value well into the future.



Motozo Shiono Chairman of the Board

Chairman of the Board and Representative Director Isao Teshirogi, Ph.D. President and CEO

# Making a positive contribution to the health of people worldwide

### Shionogi's Operating Environment

The pharmaceutical sector faces rapid and far-reaching change in its operating environment. Developments in the prescription drug sector are particularly severe. The Shionogi Group is focusing on eight key areas of change: (1) the impact of aging societies worldwide, (2) economic pressure on healthcare systems (pricing pressure), (3) the growing problem of drug-resistant bacteria and viruses, (4) rising social needs for longer healthy life expectancy, (5) greater challenges in drug discovery, (6) an accelerating pace of industry-academia collaboration, (7) an increasing number of industryindustry partnerships that include companies from other sectors, and (8) a tighter focus on therapeutic areas by major pharmaceutical companies. We will respond and adapt flexibly to these changes in our operating environment, which are listed in order of importance for Shionogi, in order to remain competitive and continue fulfilling our responsibility to society. By leveraging our strengths, we aim to raise the Group's presence in Japan – the first advanced country to face the challenges of a rapidly aging society. Using this stronger position in Japan, we will also reinforce the Group's presence globally.

### Shionogi's Growth Strategy

We launched Shionogi Group Strategy 2020 (SGS2020) in April 2014 to respond flexibly to changes in our operating environment. The strategy is reviewed annually on a rolling basis to clarify our goals for the next three years. This rolling review assesses the Group's strategic direction, performance and progress versus the plan's goals as part of a rigorous evaluation to ensure our business remains sustainable. SGS2020 is anchored by the Shionogi Group's strengths in infectious diseases, pain and CNS disorders, and small-molecule drug discovery, which have been built up over many years. Leveraging these strengths, we will work to realize our SGS2020 vision – to grow as a drug discovery-based pharmaceutical company – and the main objective of our Company Policy – to strive constantly to supply the best possible medicine to protect the health and wellbeing of the patients we serve. We believe we can make a positive contribution to the health of people worldwide by working toward those objectives on a daily basis.

June 2016

Shions

Motozo Shiono Chairman of the Board and Representative Director

Isao Teshirogi, Ph.D. President and CEO

# 01

### Strengths that increase our value to society

# A long history of addressing 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)

(1834-1931) Gisaburo Shiono, Sr. was born in 1854 in Doshomachi, Osaka. Under the guidance of his father Kichibe he learned the wholesale trade and on March 17, 1878 launched his own drug wholesaling business in Doshomachi on his 24th birthday. 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.



### 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).

# Our track record in infectious disease treatment < Infectious diseases present a real threat to human life >

In 1959, 31 years after Alexander Fleming's 1928 discovery of penicillin gave us the ability to control bacterial infections for the first time, Shionogi launched its first proprietary antibacterial agent, *Shinomin* (sulfamethoxazole). The drug was outlicensed to Roche, helping to treat patients with infectious diseases worldwide. Shionogi continued to develop antibiotics, launching FIC<sup>-1</sup> antibacterial agent *Shiomarin* (latamoxef sodium) in 1982, *Flumarin* (flomoxef sodium) in 1988, *Flomox* (cefcapene pivoxil hydrochloride hydrate) in 1997 and a range of other proprietary compounds that continue to influence our products today. Shionogi is also active in the field of antiviral treatments, developing a steady stream of FIC and LIC<sup>-2</sup> drugs such as anti-HIV agent dolutegravir, related pipeline drugs and anti-influenza drug candidate S-033188.



Shinomin

Shiomarin

- \*1 First-in-Class: Innovative medicines with particularly high novelty and efficacy that can significantly change the existing therapeutic paradigm.
- \*2 Last-in-Class: Unrivaled medicines with clear superiority over others that have the same mechanism of action.





# 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

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 Oxi/Norm 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 acne vulgaris treatment Differin.
- Launched idiopathic pulmonary fibrosis treatment *Pirespa*.

**2010–** The Third Medium-Term Business Plan Launch of multiple products developed globally and real growth.

### 2010

- Launched antiviral drug for influenza Rapiacta.
- Launched antidepressant drug Cymbalta.
  Established the PET Molecular Imaging Center at
- the Osaka University Graduate School of Medicine. • Established Shionogi Inc. (Florham Park, New



### 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 the China subsidiary.
- Launched postmenopausal vulvar and vaginal atrophy treatment *Osphena* in the US.
- Established Shionogi Singapore Pte. Ltd as the 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.*

### Our track record in pain treatment

### < Pain relief significantly improves patient quality of life >

Shionogi has been supplying prescription and OTC drugs for pain relief since before World War II. In the late 1980s, at the request of Japan's former Ministry of Health and Welfare, we switched our focus to the development of prescription narcotics for the treatment of cancer pain. At the time, prescription narcotics for cancer pain were not widely used in Japan and pharmaceutical companies were reluctant to respond to requests from the government, partly due to the negative image of narcotics. In line with the spirit of our Company Policy, we decided to take on the challenge and since then have worked to promote wider use of cancer pain treatments in Japan. Today, we supply a wide range of chronic pain treatments. We also have high hopes for *Naldemedine*, a new treatment for opioid-induced constipation (OIC) and our first-ever globally developed proprietary compound, which is set to have a positive impact on patient health worldwide.

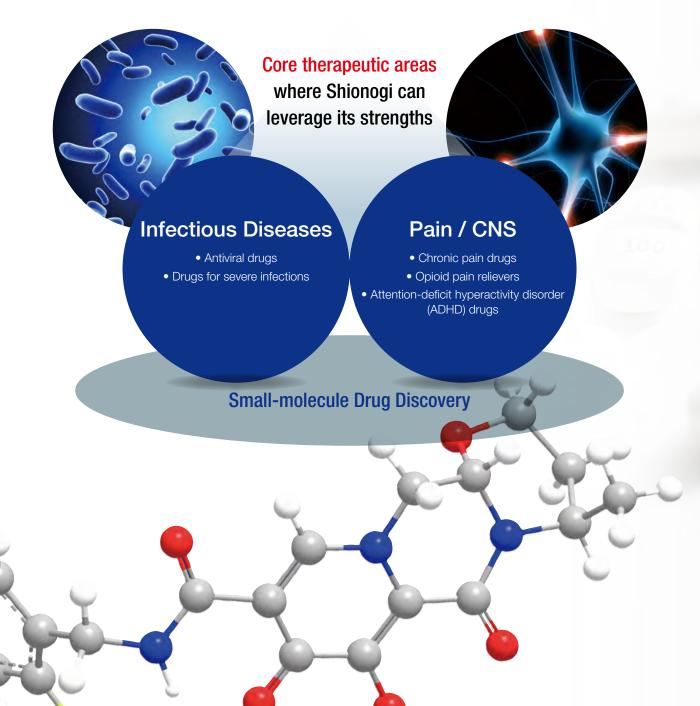


Strengths that increase our value to society

# 02

# Core therapeutic areas

We have identified a number of core therapeutic areas where Shionogi can leverage the strengths it has built up over many years. We aim to protect the health and wellbeing of the patients we serve by developing a steady stream of new medicines in the areas of infectious diseases and pain / CNS disorders.



### Drugs developed using our strengths in infectious diseases

### Tivicay and Triumeq

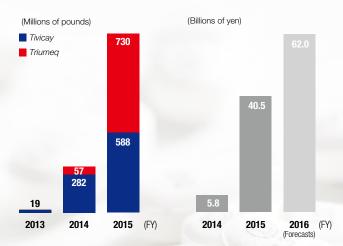
(dolutegravir) (HIV treatment) < HIV franchise products >

*Tivicay* is a new HIV integrase inhibitor with high levels of efficacy and safety and limited risk of drug resistance. Shionogi and GlaxoSmithKline (GSK) discovered the drug and developed it jointly with ViiV Healthcare. US, European and domestic HIV treatment guidelines recommend *Tivicay* as one of the first-choice drugs for treatment-naïve patients, making it an important new treatment option for all HIV-1 positive patients. As of the end of 2014, an estimated 36.9 million people were living with HIV worldwide and there are roughly 2 million new HIV infections each year.

Global sales of our HIV franchise products rose sharply in fiscal 2015, generating royalty income of ¥40.5 billion.



### Royalty income from ViiV



### Promising development compounds in the area of infectious diseases



### Drug candidate for the treatment of multidrug-resistant Gram-negative bacterial infections S-649266

S-649266 is an injectable cephem-based antibiotic shown to have excellent activity against Gram-negative bacteria, including multidrug-resistant strains such as *Pseudomonas aerugi-nosa* and *Acinetobacter*, which are already resistant to most antibiotics. The drug exploits the way Gram-negative bacteria acquire iron to move into the cell and demonstrates high stability to carbapenemases, which can break down many carbapenem- and cephem-based antibiotics.

The drug is currently in global Phase II and Phase III trials, including Japan, the US and Europe, and is on track for approval in the US in fiscal 2017. With at least 20,000 people dying each year from drug-resistant bacterial infections in both the US and Europe, we believe the drug has real potential to help save patient lives.

Japan Phase II US Phase I

# Drug candidate for the treatment of influenza S-033188

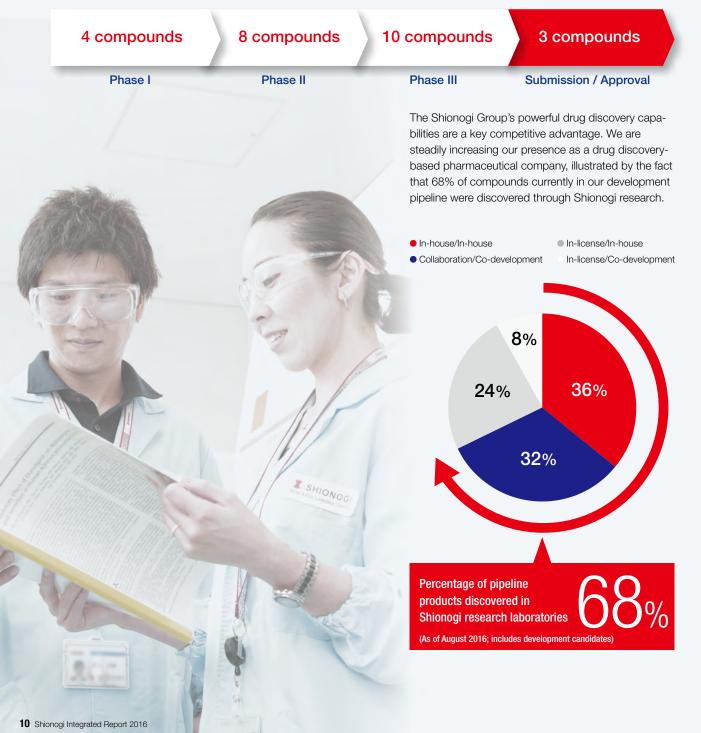
S-033188 is cap-dependent endonuclease inhibitor with a selective, novel mechanism of action that inhibits the initiation of enzymes required for influenza virus proliferation and multiplication. The drug is likely to be a one-time, single dose therapy for influenza.

S-033188 has been designated as a fast-track review candidate by Japan's Ministry of Health, Labour and Welfare and is being developed in collaboration with Roche worldwide (excluding Japan and Taiwan). The drug has completed domestic Phase II trials and is being prepared for Phase III. We plan to submit a new drug application (NDA) in Japan during fiscal 2017. Roughly 40 million people are infected by the influenza virus each year in Japan, the US and Europe, and the global market for treatments is estimated to be worth approximately ¥90 billion.

# 03 The potential of our pipeline

We are using our business resources effectively in core therapeutic areas to boost drug development success rates and increase the potential of our development pipeline. By developing drugs rapidly and efficiently and strengthening cooperation with external partners, we aim to supply new medicines to patients in need worldwide as quickly as possible.

As of August 2016



### Pipeline

(As of August 2016)

	Phase I	Phase IIa	Phase IIb	Phase III	Submission / Approval	Development stage in key markets
Infectious disease	S-649266 (Mult	idrug-resistant	tions)	Global: Phase II, III		
	S-033188 (Influ	enza virus infec	Japan: Phase II, USA: Phase I			
Pain / CNS	S-877503 (Pedi	iatric ADHD⁺¹)				Japan: Submission (January 2016)
	Cymbalta (Pain	associated wit	h osteoarthritis	)		Japan: Submission (February 2016)
	Naldemedine (	Opioid-induced	constipation)			Japan: Submission USA: Submission (March 2016)
	S-877489 (Pedi	iatric ADHD <sup>•1</sup> )				Japan: Phase III
	S-877503 (Adu	lt ADHD⁺1)				Japan: Phase III
	S-120083 (Infla	mmatory pain)				Japan: Phase I, USA: Phase I
	S-010887 (Neu	ropathic pain)				Japan: Phase I
	S-117957 (Inso	mnia)				USA: Phase I
	S-600918 (Neu	ropathic pain)				Japan: Phase I
Metabolic disorder	S-237648 (Obe	sity)				Japan: Phase II, USA: Phase I
	S-707106 (Type	e 2 diabetes)				USA: Phase IIa
Frontier	Lusutrombopa	g (Thrombocyto	penia associate	ed with chronic	liver disease)	Global: Phase III
	Osphena (Vagir	nal dryness ass	USA: Phase III			
	Actair (Pediatri	c patients with	perennial allerg	ic rhinitis cause	ed by HDM)	Japan: Phase III
	S-588410 (Eso	ohageal cancer	)			Japan: Phase III
	S-555739 (Aller	gic rhinitis)				Japan: Phase III, USA: Phase IIa, Europe: POM <sup>2</sup>
	S-588410 (Blad	lder cancer)				Japan/Europe: Phase II
	S-525606 (Allergic rhinitis caused by Japanese cedar allergen)					Japan: Phase II
	S-488210 (Head	d and neck squ	amous cell card	inoma)		Europe: Phase I / II
	S-222611 (Mali	gnant tumor)				Europe: Phase I / II
Out-Licensing Activity	S/GSK1265744 LAP'3 (For the treatment and prevention of HIV infection)					USA: Phase II
	S-0373 (Spinoc	erebellar ataxia	a)			Japan: Phase III
	Janssen/Shion	ogi BACE inhibi	itor (Alzheimer's	disease)		Global: Phase II / III

\*1 ADHD: Attention-deficit hyperactivity disorder \*2 POM: Proof of mechanism \*3 LAP: Long-acting parenteral formulation

### **Performance Highlights**

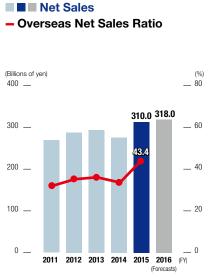
### **Earnings: Key Points**

### Net sales of ¥310 billion above forecast

- Growth in royalty income on the back of rising global sales of HIV franchise products
- Sales growth in Japan, centered on strategic products

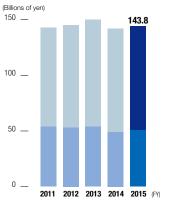
### **Record-high operating income**

- Profit targets achieved in domestic and overseas operations
- Rigorous cost control in all areas (selling, general expenses, research and development expenses)



### Selling, General and Administrative **Expenses**

R&D Expenses Selling and General Expenses

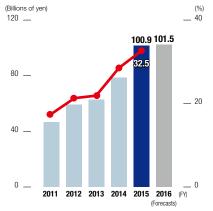


### Operating Income Operating Income Ratio



### Ordinary Income<sup>\*1</sup> - Ordinary Income Ratio



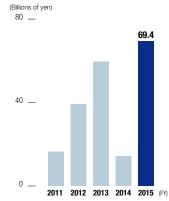


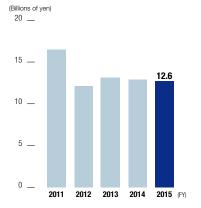
Profit Attributable to Owners of Parent\*2

Profit Attributable to Owners of **Parent Ratio** 

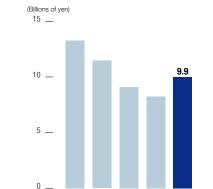


Free Cash Flow<sup>\*3</sup>





Depreciation and Amortization



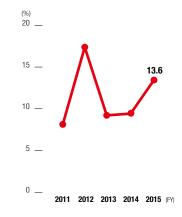
2014

2015 (FY)

2011 2012 2013

Liabilities

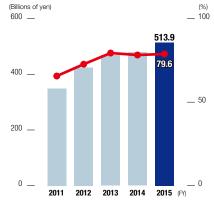
Capital Investments

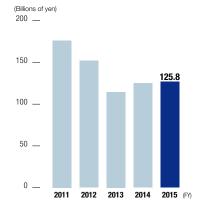


- ROE<sup>\*2</sup>

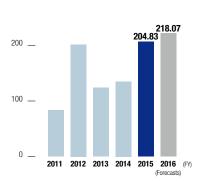
(yen) 300 \_\_\_

Total Net assetsEquity ratio

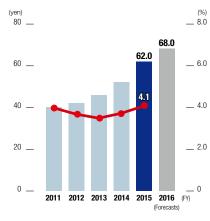




Profit Attributable to Owners of Parent per Share<sup>2</sup>



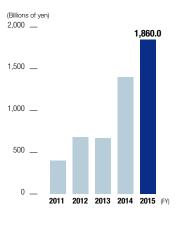
Dividends per Share
 Dividend on Equity Ratio



- Payout Ratio



Market Capitalization (Fiscal years ended March 31)



\*1: Ordinary income is an item in financial statements based on Japanese GAAP.

\*2: In fiscal 2012, taxes and other expenses declined due to the booking of losses on the valuation of shares of subsidiaries. The losses,

booked by the parent company, were related to the revaluation of operations in the US.

\*3: Free cash flow = Net cash provided by operating activities + Net cash used in investing activities

### Message from the President

**Isao Teshirogi, Ph.D.** President and CEO

### **New Medium-Term Business Plan**



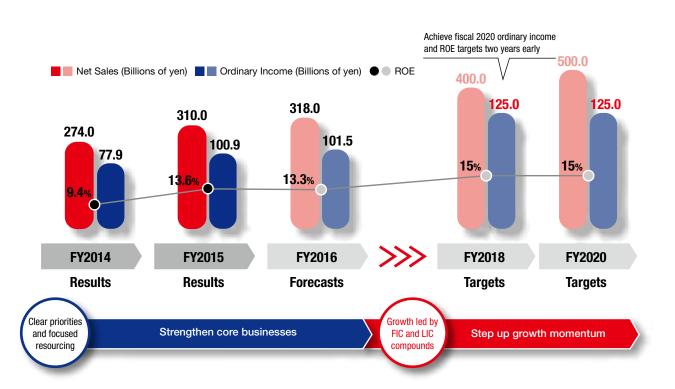
FY2014

### Steady progress toward our 2020 objectives

Two years have passed since the April 2014 launch of SGS2020, which is aimed at realizing our Company Policy worldwide – to strive constantly to supply the best possible medicine to protect the health and wellbeing of the patients we serve. SGS2020 sets out the path to achieving our vision for Shionogi in 2020. That vision is very clear: we want to grow as a drug discovery-based pharmaceutical company. To realize that vision, we have positioned infectious diseases and pain / CNS disorders as core therapeutic areas. We are channeling business resources into those treatment fields and sales areas in order to originate a steady stream of new FIC and LIC compounds that can drive growth in the future. We will also enhance our operational capabilities in all businesses. We aim to continuously create scientific and business innovation to secure our growth.

We made significant progress in fiscal 2015, the second year of SGS2020. An anti-HIV drug developed with GlaxoSmithKline (GSK) of the UK gained momentum among patients and frontline medical professionals worldwide, supporting steady growth in global sales at ViIV Healthcare, leading to higher royalty income. We also received royalty income from UK company AstraZeneca for *Crestor* and sales of prescription drugs were firm in Japan.

With SGS2020, we have adopted a rolling plan rather than a fixed medium-term management plan. Each year, we review our business objectives for the next three years, allowing us to respond flexibly to the rapid changes in our operating environment. Under our rolling plan for fiscal 2018, which was announced in May 2016, we aim to achieve our SGS2020 final-year targets for ordinary income and ROE two years early.



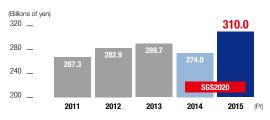
# Net sales top ¥300 billion, record-high operating and ordinary income

We reported net sales of ¥310.0 billion in fiscal 2015, beating our target. Sales topped ¥300 billion for the first time since 2002, when we sold our drug wholesaling subsidiary, Ohmori Co., Ltd. Operating income was a record-high ¥91.4 billion, higher than the peak in fiscal 2013 and ordinary income was ¥100.9 billion, marking the fourth consecutive year of record profits.

Another one of our goals is to be profitable at the operating income level excluding royalties from *Crestor* and HIV franchise products. We achieved this in fiscal 2015 with operating income of ¥3.3 billion, exceeding our initial forecast by ¥5.3 billion. Return on equity (ROE) is another performance benchmark in SGS2020. In fiscal 2015, ROE was a high 13.6%, significantly above our fiscal 2017 rolling plan target of 12% announced last year. This strong ROE figure reflected a number of factors, including growth in royalty income driven by higher global sales of HIV franchise products, steady royalties from *Crestor* on par with the level in fiscal 2014, an improvement in the earnings structure due to revised contract terms for *Cymbalta*, and milestone payments for candidate compounds licensed to other companies.

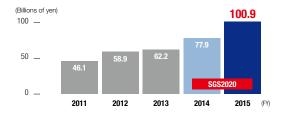
Research and development was also largely in line with our targets at the start of the fiscal year. Highlights included new NDAs in Japan and the US for *Naldemedine*, Shionogi's first globally developed proprietary compound. *Naldemedine* will be a key test of our global vision for Shionogi in SGS2020 – to grow as a drug discovery-based pharmaceutical company.

Fiscal 2016 will not be easy due to drug price revisions in Japan and the end of our US patent for *Crestor*. However, we remain committed to our bottom-line targets and we will work to generate further top-line growth by strengthening Shionogi's presence in the core therapeutic areas of infectious diseases and pain and CNS disorders in domestic and overseas markets.

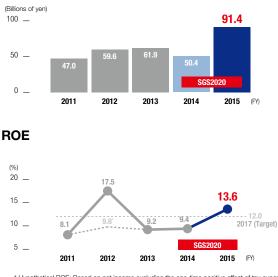


### Net Sales





### **Operating Income**



### **Reinforcing Our Operating Structure**

# Enhancing cost management and stepping up efforts to drive top-line growth

In fiscal 2015, we were profitable at the operating income level excluding royalties from *Crestor* and our HIV franchise products. That achievement is the result of tighter cost control – one of our new strengths as a Company – and tireless business process innovation from a zero base.

In cost management, research and development costs are not off-limits, even though we are working to become a drug discovery-based pharmaceutical company. We also prioritize some spending in selling, general and administrative expenses based on a comprehensive, Group-wide analysis of investment outcomes. We aim to take this cost control even further by embedding cost management across our operations.

Top-line growth will also have a role to play as we continue to strengthen our operating structure in fiscal 2016 in order to reduce our dependence on royalty income.



# Building an operating structure to support medium- and long-term growth

Strengthen the pipeline in core therapeutic areas Scientific Innovation

Remain profitable at the operating income level excluding royalties Business Process Innovation

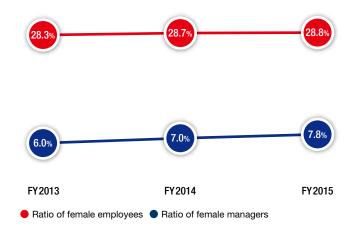
Firm commitment to bottom-line targets Shift from Cost Control to Cost Management Provide value for all stakeholders

### Harnessing diverse talent to deliver innovation

Continuous innovation is the vital ingredient to ensure companies remain viable and continue fulfilling their responsibility to society. At Shionogi, we are focusing on diversity as the driving force of innovation. Bringing together diverse values and perspectives can give birth to a wide range of innovation through friendly competition. This innovation can be used to benefit patients and society, which also translates into a sustainable future for Shionogi. That's why we are focusing on developing diverse personnel. Specific initiatives include the President's Management Seminar and the Management Seminar. The President's Management Seminar, led by me, was set up to train senior managers, while the Management Seminar is run by division heads who conduct training programs to foster Shionogi's future leaders. We also provide a wide range of opportunities for younger employees to compete with their peers so that the best rise to the top, giving them training to become future managers as part of a comprehensive program of succession planning. In this way, we provide training to nurture the next generation of leaders, aiming to cultivate diverse human resources and sustain our business.

We also actively support women in the workplace, leading to a rising share of women in our workforce and in management positions. We believe sharing and bringing together different values regardless of gender will generate innovation that drives Shionogi's growth in the future.

These initiatives have won praise from outside the Company. In fiscal 2015, Shionogi was selected by Japan's Ministry of Economy, Trade and Industry as one of the firms in its Diversity Management Selection 100 project. The City of Osaka, where our head office is located, also certified Shionogi as a company that plays a leading role in supporting the active participation of women in the workplace. We aim to make Shionogi even more diverse in terms of gender, age and nationality. We will harness that diversity to generate continuous innovation that sustains the Group and allows us to fulfill our responsibility to society.



### **Ratio of Female Employees / Ratio of Female Managers**



### Aiming to achieve the best possible corporate governance Steadily increase dividends in line with earnings growth

The Shionogi Group has put in place a corporate governance structure to realize its Company Policy – the Group's corporate philosophy – on a global basis. Also, in October 2015, we established the Group's Basic Views and Guidelines on Corporate Governance in accordance with the spirit of the Corporate Governance Code, which was released in June 2015. In line with those principles, we are working to realize the best possible corporate governance based on transparent, fair, timely and decisive decision-making.

Shionogi's Board of Directors has six members, including three outside directors. Those outside directors, who make up half of the board, have a very important role to play in ensuring fair and efficient management. We are improving information-sharing with outside directors, such as holding meetings to exchange information and seminars about the Group, giving them more detailed insight into Shionogi's operations to help them fulfill their duties and responsibilities.

We promote constructive dialogue with shareholders and investors to deepen their understanding of our business and research and development efforts. By carefully communicating our approach and policies, we aim to enhance governance through high-quality dialogue that helps us meet our responsibility to all stakeholders.

At the same time, we work to ensure Shionogi is trusted by society through rigorous compliance by all Shionogi people globally, which also helps us fulfill our responsibility to shareholders.

The Shionogi Group uses profits generated by improvements to business operations to reward shareholders. These profits are also used in a balanced manner to invest in future growth and to make strategic business investments, further reinforcing the business base and maximizing corporate value. Based on our policy of steadily increasing dividends in line with growth, using the dividend on equity (DOE) ratio as our priority benchmark, we raised the full-year dividend by ¥10.0 per share to ¥62.0 for fiscal 2015.

I hope we can count on your continued support and understanding as we implement initiatives to increase corporate value even further.

# •

### **Basic Policy on Allocation of Profits**

Fiscal 2015 dividend: ¥62.00 per share

Fiscal 2016 dividend (forecast): ¥68.00 per share (interim dividend: ¥34.00, year-end dividend: ¥34.00)

	FY 2014	FY 2015	FY 2016 (Forecasts)
Profit attributable to owners of parent	44.1 billion yen	66.7 billion yen	71.0 billion yen
Dividend per share	52.00 yen	62.00 yen	68.00 yen
Payout ratio	39.2%	30.3%	31.2%
DOE	3.7%	4.1%	4.1%
ROE	9.4%	13.6%	13.3%

• Maximize corporate value by balancing shareholder returns, investment for growth and strategic business investment

 Implement flexible shareholder return policies so shareholders have a stake in Shionogi's mediumand long-term growth

### **Progress in Fiscal 2015 and Strategy for Fiscal 2016**



Takuko Sawada Director of the Board, Senior Executive Officer, Senior Vice President, Corporate Strategy Division

### Message from the Head of the Corporate Strategy Division

In April 2015, we positioned the Corporate Strategy Meeting as a key discussion body for important issues related to business execution. This step was taken to help us achieve the targets in our new Medium-Term Business Plan, Shionogi Growth Strategy 2020 (SGS2020). We also established the Corporate Strategy Division to operate and manage the Corporate Strategy Meeting. The Finance & Accounting Department, Human Resources Department, Corporate Planning Department, Corporate Communications Department, Office of the Secretary and Product Portfolio & Planning Unit were all folded into the new Corporate Strategy Division (in April 2016, the Product Portfolio & Planning Unit was renamed the Development Portfolio & Planning Unit and was integrated into the Global Pharmaceutical Development Division).

In fiscal 2015, we achieved our fiscal 2015 sales target and our fiscal 2017 ordinary income and return on equity (ROE) targets two years early. We reported ordinary income of ¥100.9 billion and ROE of 13.6%, compared with our fiscal 2017 targets of ¥90 billion and 12%, respectively. This underscores the progress we have made tackling three key issues: strengthening our business base in Japan, strengthening our ability to cultivate new global products, and developing an operating structure independent of royalty income.

Steps to strengthen our business base in Japan are helping us steadily adapt to change and are starting to yield results. In fiscal 2015, sales from *Crestor* exceeded ¥100 billion for the second consecutive year (total sales at Shionogi and AstraZeneca, list price basis). We also strengthened promotional activities for *Cymbalta* and put in place a new domestic business structure that will allow us to contribute to healthcare at the local level.

In the second area, strengthening our ability to cultivate new global products, *Osphena* was the only drug to register growth in prescriptions in the shrinking market for postmenopausal vaginal atrophy treatments. We are still in the early stages of reaping benefits from new development compounds, but we made some progress, including NDAs in Japan and the US for *Naldemedine* and the start of global Phase III trials for S-649266, a drug candidate for the treatment of multidrug-resistant Gram-negative bacterial infections, which is becoming a serious public health issue worldwide.

In the third area, developing an operating structure independent of royalty income, we returned to profit at the operating income level, excluding royalty income, and achieved a marked improvement in the cost of sales ratio. We will continue to raise awareness across the Group about improving cost control while taking our approach even further by embedding cost management across our operations.

However, we still need to improve top-line growth.

In fiscal 2016, we aim to finish strengthening our core businesses. One of our goals in SGS2020 is to select and concentrate resources on strategic areas. We remain committed to our bottom-line target by stepping up cost management, but we will also cultivate growth drivers in our domestic and overseas operations by generating sales from drugs such as *Naldemedine* and new ADHD treatments, as well as from existing drugs.

### **Outcomes of Key Initiatives in Fiscal 2015**

# Strengthen our business base in Japan

- Expanded indications and strengthened promotional activities for *Cymbalta*
- Focused medical representative resources on *Mulpleta* and *Actair*, two new strategic products
- Secured approval for *Crestor OD* tablets, submitted NDA for S-877503
- Reorganized domestic operating structure to enable Shionogi to contribute to new focus on local healthcare provision

Strengthen our ability to cultivate new global products

 Achieved growth in total prescriptions for *Osphena* through evidence-based marketing and stepped up purchasing support

- Submitted NDAs for *Naldemedine* in Japan and the US
- Advanced global development of S-649266 and lusutrombopag
- Signed license and collaboration agreement with Roche for S-033188
- Revised contract terms for RSC-435830 (GSK3342830)

### Develop an operating structure independent of royalty income

- Returned to profit at the operating income level excluding royalty income
- Achieved a marked improvement in the cost of sales ratio
- Achieved inventory turnover of 6.8 months
- Improved cost management

### Fiscal 2015 Review and Key Actions for Achieving SGS2020



Key Actions for Achieving SGS2020

Complete work on strengthening core businesses Achieve top-line growth targets in domestic and overseas business while remaining committed to bottom-line targets

# Research

# Driving forward drug discovery to consistently identify new FIC and LIC compounds



Takeshi Shiota, Ph.D. Corporate Officer, Senior Vice President, Pharmaceutical Research Division

### Progress in Fiscal 2015

In the past fiscal year, we continued to create new drug development candidates focusing on two of our core therapeutic areas – infectious diseases and pain and CNS disorders. At the same time, we advanced research to maximize the value of new drug development candidates that have the potential to become FIC or LIC drugs. We also actively participated in joint research projects with external partners in order to boost research productivity and improve the accuracy of drug performance forecasting.

In the area of infectious diseases, we discovered two drug candidates for the treatment of multidrug-resistant Gram-negative bacterial infections in collaboration with GSK. We will progress the development of S-649266 as a new drug development candidate and GSK will separately progress the development of a backup drug candidate. Both compounds, which have different profiles, have the potential to contribute to the treatment of serious infectious diseases in the area of Gram-negative bacterial infections, which have become a major public health challenge worldwide. In the area of pain and CNS disorders, we worked to strengthen our pipeline, identifying a drug development candidate for the treatment of central neuropathic pain and a new BACE<sup>-1</sup> inhibitor candidate for the treatment of Alzheim-er's disease, discovered in collaboration with US company Janssen Pharmaceuticals.

As part of our efforts to improve research productivity, we established a joint research project to discover new opioid analgesics with Pionnier, a carve-out venture<sup>-2</sup> created by the Osaka Chamber of Commerce and Industry and other partners, and we started working with Nissan Chemical Industries, a company with strong capabilities in compound design and organic synthesis, to identify new antifungal agents. We also began collaborating with Pepti-Dream, aiming to build on our already strong position in small-molecule drug development.

These initiatives are just some of the steps we took in fiscal 2015 to advance proprietary research and generate synergies with partners that fit well with our strengths, aiming to build a pipeline of drugs for the medium and long term and reinforce our manufacturing capabilities.

\*2 A type of venture company formed by spinning off a promising business to generate further growth. The original company typically maintains links with the carved out business.

### **Objectives for Fiscal 2016**

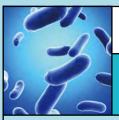
We aim to discover two or more drug development candidates in target therapeutic areas in SGS2020, as well as strengthen drug discovery capabilities through new collaborations with academia and industry in Japan and overseas, helping us advance research that generates a steady stream of potential FICs and LICs.

### Drug discovery capabilities that lead to groundbreaking new drugs

The development of dolutegravir was led by the finding that an HIV integrase inhibitor binds to active sites. 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 dolutegravir. This also prompted us to initiate research into compounds that inhibit the cap endonuclease of the influenza virus based on evidence of the same binding behavior. Our research team, confident that they could use the same approach for influenza drug development as they had in HIV drug development, took their know-how from dolutegravir in a new direction, resulting in the discovery of anti-influenza drug candidate S-033188. This illustrates how passing on and cultivating expertise is a key part of our approach to small-molecule drug discovery at Shionogi.

FOCUS ON

01



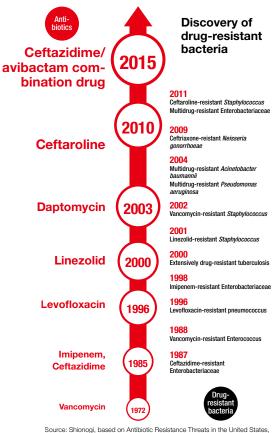
### Taking on new challenges in infectious diseases

# Fighting the global threat of infections

Multidrug-resistant bacteria, tuberculosis and malaria are a growing threat to human health worldwide. Outbreaks of emerging infections such as the Ebola, Zika and Dengue viruses are also a serious public health issue that threatens human life. The issue of multidrug-resistance needs to be tackled urgently on a global scale and has been flagged as a serious problem by the World Health Organization (WHO) and the leaders of the G7 nations.

Meanwhile, many global pharmaceutical companies have withdrawn from drug discovery in the field of infectious diseases, as treatment periods tend to be short, limiting opportunities for profits. Against this backdrop, the Shionogi Group is leveraging its long track record in the field to actively develop new treatments for infectious diseases. Specifically, two compounds have progressed to late stage global development. One is S-649266, a promising candidate for the treatment of multidrug-resistant Gram-negative bacterial infections such as multidrug-resistant Pseudomonas aeruginosa and multidrug-resistant Acinetobacter baumanii for which there are currently no treatment options. The other is S-033188, which has been shown to be highly effective against the influenza virus, a pandemic risk. Shionogi is actively involved in the search for treatments for multidrug-resistant tuberculosis and pathogens that cause neglected tropical diseases (NTDs) through industry-academic collaborations and other partnerships.

We will continue to focus on drug discovery in this field in order to rapidly develop new treatments, aiming to help as many people as possible conquer these life-threatening diseases.



Source: Shionogi, based on Antibiotic Resistance Threats in the United States, 2013, Centers for Disease Control and Prevention

	Research areas	Unmet medical needs and disease background	Research strategy
Severe Infections	<ul><li>Bacterial infections</li><li>Fungal infections</li></ul>	<ul> <li>Requirement for</li> <li>Drugs for antibiotic-resistant bacteria</li> <li>Improvement in compliance (early hospital discharge, high barrier to the development of resistance)</li> <li>Safe and efficacious antifungal drug</li> </ul>	<ul> <li>Develop drugs for antibiotic- resistant bacteria by β-lactam chemistry</li> <li>Develop drugs for fatal systemic fungal infections</li> </ul>
Viral Infections	• HIV • Respiratory virus	<ul> <li>Increased risk of HIV infection with lifestyle changes</li> <li>Requirement for</li> <li>Improvement in QOL* of HIV patients (long-term use, long administration interval, high barrier to the development of resistance)</li> <li>Efficacious drugs for respiratory virus infection</li> </ul>	<ul> <li>Expand HIV pipeline by FIC/LIC drug discovery</li> <li>Develop anti-respiratory virus drugs by original compound design</li> </ul>
Emerging Infections	<ul> <li>Emerging/re-emerging infectious disease</li> </ul>	<ul> <li>Outbreak of emerging/re-emerging infectious diseases</li> <li>Requirement for efficacious drugs</li> </ul>	Drug discovery through external collaborations

### Shionogi's infectious disease target research areas

\* QOL: Quality of Life

# Development

# Contributing to society as one of the world's leading pharmaceutical companies in infectious disease treatments



Kazuhiro Hatanaka Corporate Officer, Senior Vice President, Global Development Division

### **Progress in Fiscal 2015**

Almost all our development projects advanced as planned in fiscal 2015. In global drug development, we submitted NDAs in Japan and the US for *Naldemedine*, a treatment for opioid-induced constipation (OIC). Global Phase III trials progressed smoothly for thrombocytopenia treatment *Mulpleta* and for S-649266, a treatment for multidrug-resistant Gram-negative bacterial infections. We also entered into a global license and collaboration agreement with Roche to develop and commercialize anti-influenza drug S-033188, which has been designated for priority review by the Ministry of Health, Labour and Welfare in Japan. A Phase II trial in Japan for S-033188 confirmed sufficient evidence of efficacy and safety to progress to the next stage of clinical trials.

*Cymbalta,* one of our strategic products in Japan, was approved for the additional indications of pain associated with fibromyalgia and chronic lower back pain, and we submitted an NDA for the additional indication of pain associated with osteoarthritis. *Mulpleta* was granted approval in Japan and we submitted an NDA for S-877503 for the treatment of attention-deficit hyperactivity disorder (ADHD).

### **Objectives for Fiscal 2016**

In fiscal 2016, we will push ahead with the global development of S-649266 and S-033188, aiming to continue making a significant contribution to society as one of the leading pharmaceutical companies in infectious disease treatments worldwide. In pain and CNS disorders, one of our core therapeutic areas, we plan to submit an NDA in Japan for S-877489, another ADHD treatment but with a different mechanism of action than S-877503. We will also apply for non-cancer pain indications for *OxyContin* and for abuse-deterrent *OxyContin* formulations.

To continue implementing high-quality, expeditious clinical trials, we will strengthen global operations and adopt standardized processes. We will also generate further efficiency gains and improve cost management to ensure patients worldwide have access to the best possible medicines.

### NDAs submitted for Naldemedine in Japan and the US

*Naldemedine*, an original Shionogi compound, moved into human clinical trials in 2009. Since then, the drug has been tested in a total of 22 clinical trials in 18 countries worldwide, involving over 3,000 healthy subjects and patients with OIC. The COM-POSE program, launched in 2013 in Japan, the US and Europe, is the first-ever global program of Phase III clinical trials for an original Shionogi compound run solely by the Shionogi Group. Following the trials, we submitted NDAs in Japan and the US in March 2016. We have positioned *Naldemedine* as a first-in-class (FIC) and last-in-class (LIC) drug in Japan and as an LIC drug in the US, aiming to help patients suffering from OIC gain access to the best possible treatment. In 2017, we expect *Naldemedine* dine to improve QOL for patients with OIC, giving them an effective and safe treatment while having no adverse impact on the analgesic mechanism of opioids.

# CMC

# Using high value-added "enhanced product development" to address today's healthcare needs



Miyuki Hiura Corporate Officer, Senior Vice President, CMC Research Division

### **Progress in Fiscal 2015**

The CMC Research Division plays a vital role in realizing Shionogi's vision for creating and producing even better medicines.

The progress we made in fiscal 2015 underscored the global competitiveness of our technologies. We submitted NDAs for *Naldemedine* in Japan and the US in line with our planned timeframe and our technologies supported significant advances in the development of anti-influenza drug candidate S-033188, which is designated a fast-track review candidate under Japan's priority review system. S-033188 was developed at unprecedented speed and we were able to significantly reduce the cost of synthesizing active pharmaceutical ingredients.

We also prepared new investigational drugs in a timely manner for S-649266 Phase III clinical trials in accordance with rules for multiple jurisdictions. In addition, we made solid progress in NTE development\*, which brings together all our drug formulation technologies, helping us take an important first step on the road to building a hybrid business model encompassing both new drug discovery and NTE development.

\*New therapeutic entity development: Development of new dosage forms, new administration routes and new indications with known compounds.

### **Objectives for Fiscal 2016**

As the pace of global drug development accelerates, we have been given a greater role in delivering high-quality, easy-to-use medicines that satisfy the needs of patients and medical professionals worldwide. In line with this wider role, the CMC Development Laboratories was renamed the CMC R&D Division, effective from the start of fiscal 2016. In the year ahead, we will push forward with the strategic development of new drugs and NTE development, focusing on the establishment of commercial production processes for abuse-deterrent *OxyContin* formulations, approval for *Naldemedine* and the steady development of S-033188. We will use our high value-added "enhanced product development" approach to address today's healthcare needs, aiming to deliver superior drugs that improve QOL for patients in need of new treatments.

Note: CMC (Chemistry, Manufacturing and Control) : Drug substance manufacturing process studies, pharmaceutical development studies, and quality control studies

### **Enhanced Product Development**

We achieved a number of positive outcomes in fiscal 2015. We improved the absorbability of *Mulpleta's* active pharmaceutical ingredient, which dissolved slowly in the gastrointestinal tract. Building on our existing research in absorption enhancement technology, we developed a formulation that adds a solubilizing agent to the active pharmaceutical ingredient, improving absorption and helping to improve patient health. With *Crestor* orally disintegrating (OD) tablets, we created the world's first trilayer OD tablet that fully disintegrates in the mouth. The active pharmaceutical agent is contained in a middle layer, while the top and bottom layers contain sweetening agents that also protect the drug from light. We also successfully developed *Naldemedine*, which demonstrates high levels of stability and homogeneity for an ultra-low dose drug, and pushed ahead with the development of S-649266 using our strengths in freeze-drying technologies. Going forward, we will continue to leverage technologies that enhance the performance, stability and absorbability of active pharmaceutical ingredients to develop superior medicines.

First trilayer OD tablet for *Crestor* in the world



# Manufacturing

# Using upcoming new drug launches as an opportunity to demonstrate our sophisticated manufacturing technologies



Takuo Fukuda Executive Officer, Senior Vice President, Manufacturing Division

### **Progress in Fiscal 2015**

We launched a number of new drugs in fiscal 2015, including *Actair* and *Mulpleta*. We also secured marketing approval for *Crestor* orally disintegrating (OD) tablets, one of our strategic lifecycle management (LCM) products. The new *Crestor* OD tablets were launched in June 2016. The Manufacturing Division made a significant contribution to the launch of these new products in the past fiscal year, in line with the goal of "producing the best possible medicines" in the Company Policy of Shionogi.

We also pushed ahead with our Mother Factory Concept<sup>11</sup> aimed at ensuring stable supplies of high-quality products. Under this concept, the production of long-listed drugs has been outsourced to external contract manufacturing organizations (CMOs). <sup>11</sup> Mother Factory Concept: A manufacturing strategy that allows us to respond flexibly to fluctuations in sales volumes throughout the product

lifecycle. This involves actively using CMOs worldwide to manufacture Shionogi products when capacity is exceeded at proprietary plants.

### **Objectives for Fiscal 2016**

A number of new products are planned for NDA or launch in fiscal 2016 and beyond. We have to be ready to start commercial production at our Kanegasaki Plant and Settsu Plant and also at Shionogi Pharma Chemicals Co., Ltd, a Shionogi consolidated subsidiary.

Our anti-influenza drug candidate S-033188 has been designated as a fast-track review candidate under Japan's priority review system and S-649266, a candidate for the treatment of multidrug-resistant Gram-negative bacterial infections, has been designated as a qualified infectious disease product (QIDP)<sup>2</sup> by the US Food and Drug Administration (FDA). This highlights the significant potential of both drug candidates. We are also preparing to support the launch of *Naldemedine*, an OIC treatment for which we have simultaneously submitted NDAs in both Japan and the US. We are putting in place a production system that will be compliant with regulations in each market.

In Japan, Shionogi is targeting the early launch of two attention-deficit hyperactivity disorder (ADHD) drug candidates, S-877503 and S-877489.

Using this almost unprecedented number of upcoming drug launches, we aim to demonstrate Shionogi's strengths in manufacturing technologies over the next few years and is therefore a crucial period for the Manufacturing Division.

We are committed to delivering new Shionogi drugs to patients as rapidly as possible. Everyone in the Manufacturing Division will work as one to achieve this goal with our upcoming drug launches, while also cooperating closely with related divisions.

\*2 New drugs developed to treat drug-resistant infectious diseases that are granted this status are eligible to receive five years of marketing exclusivity in addition to certain exclusivity already provided under US law.



# FOCUS ON

# 02

### Strengths and features of shionogi's manufacturing sites

### Kanegasaki Plant

### Integrated production of B-Lactam antibiotics

The Kanegasaki Plant has an integrated production system for cephem- and carbapenem-based antibiotics, covering active pharmaceutical ingredients (API), formulation manufacturing and packaging. This allows us to deliver high-quality products to patients worldwide.

The operating environment surrounding B-Lactam antibiotic production in Japan has changed in recent years, with a growing number of companies deciding to withdraw from domestic production of API due to tighter regulations and the rising cost of production. These drug companies now import API from China, South Korea and India and then complete the manufacturing process in Japan. However, we remain committed to our integrated manufacturing approach at the Kanega-



saki Plant, including the production of API. Overseas production has cost benefits, but we are concerned about the risk of API quality issues and potential obstacles to stable supplies. Our integrated production system allows us to rapidly resolve any issues that may arise in production by working closely and quickly with teams inside the Company, minimizing the risk of supply shortages. Also, our "Shionogi quality" approach is not limited to the quality of finished products. It also includes environmental protection, such as reducing energy consumption and CO<sub>2</sub> emissions in our manufacturing activities, and ensuring safe and healthy working environments for personnel at all our plants.

The Kanegasaki Plant has started preparing for commercial production of S-649266, a drug candidate currently under global development for the treatment of multidrug-resistant Gram-negative bacterial infections. This drug will also be manufactured by the plant's integrated production system. Everybody at the Kanegasaki Plant is committed to rapidly starting production of S-649266 so that people suffering from multidrug-resistant infections worldwide will be able to access the drug as soon as possible.

By maximizing our strengths as a Company - strong research capabilities in infectious diseases and integrated production technologies covering API, formulation manufacturing and packaging - we will fight the global threat of emerging infectious diseases and multidrug-resistant infections.

### Settsu Plant

A flexible production system that can handle small batch manufacturing and multiple products

The Settsu Plant manufactures pharmaceutical products (except antibiotics) in tablet, capsule and injectable forms in accordance with PIC/S<sup>\*1</sup> and GMP<sup>\*2</sup>. Using flexible production facilities and technologies that can handle small batch manufacturing and multiple product lines, the Settsu Plant constantly seeks to improve productivity and deliver strategic products such as Cymbalta and Irbetan to patients.



The Settsu Plant played a key role in the launch of several new drugs recently: Actair in November 2015, Mulpleta in December 2015 and Crestor OD tablets in June 2016.

Going forward, the plant will continue to use its experience and expertise in drug manufacturing, including safety and the environment, to play its part in maintaining "Shionogi quality." Specifically, the Settsu Plant will work to ensure the rapid launch of upcoming global drugs, such as anti-influenza drug candidate S-033188, OIC drug Naldemedine and ADHD drug candidates S-877503 and S-877489.

By establishing highly efficient manufacturing processes and supplying the best possible medicines, we will help to protect the health and wellbeing of patients worldwide.

\*1 The Pharmaceutical Inspection Convention and Pharmaceutical Inspection Cooperation Scheme \*2 GMP (Good Manufacturing Practice)

# **Global SCM**

### Ensuring the stable supply of products in the global market and contributing to profits



Takayuki Yoshioka, Ph.D. Executive Officer, Senior Vice President, Global SCM Division

### **Progress in Fiscal 2015**

The mission of the Global SCM Division is to contribute to customer satisfaction and help the "Shionogi family" generate profits by continuously optimizing the global supply chain around the stable supply of products.

In fiscal 2015, we strategically reviewed contracts and purchasing conditions with our domestic and overseas suppliers and overhauled logistics operations. This generated cost savings that helped Shionogi achieve profitability at the operating income level excluding royalty income. By optimizing inventories further, we reduced inventory assets and contributed to stronger cash flow. The Global SCM Division also helped to drive sales growth by reinforcing the manufacturing system for the active pharmaceutical ingredient in anti-HIV agent *Tivicay*, ensuring stable supplies. Ahead of the planned launch of *Naldemedine*, a new treatment for opioid-induced constipation, we put in place a global sales and supply chain structure.

### **Objectives for Fiscal 2016**

One of our goals is to reinforce global supply chain management functions to support the smooth launch and stable supply of Shionogi's growing portfolio of proprietary drugs. We have therefore positioned fiscal 2016 as a crucial year to push ahead with our mission and build a supply chain system that ensures Shionogi achieves its SGS2020 targets. We will work to link procurement, manufacturing and distribution functions more closely to create a fully optimized supply structure that also takes into account the requirements of business continuity plans (BCPs).

In Japan, *Crestor* OD tablets have been launched and *Cymbalta* has been approved for additional indications. Overseas, *Naldemedine* is on track for launch after other recent global drug launches such as antibiotic *doripenem* and *Osphena*. Our mission at the Global SCM Division is to ensure patients worldwide continue to have access to these and other drugs. Partnering with other Shionogi business divisions will be crucial to achieving this mission.

### Powerful SCM Capabilities—Supporting Shionogi's Bottom Line

Starting in fiscal 2014, we consolidated SCM functions within the Global SCM Division. This created a joint management system that integrates the Group's supply chain from upstream through to downstream areas. Effective fiscal 2016, the division was reorganized into two departments, the Supply Business Strategy Department and the Supply Operation Department, to strengthen our business strategy and supply operation functions.

The Global SCM Division will work in tandem with the Manufacturing Division to launch new cost control initiatives, including from a medium- and long-term perspective, in order to deliver further cost savings. Through collaboration with other divisions, we aim to develop and promote manufacturing strategies tailored to various product lifecycles and markets to ensure efficient allocation of resources, helping Shionogi to achieve its business plan targets and generate profits.

# **Quality Assurance**

Protecting patient health and the Shionogi brand at all levels of the value chain, from research and development through to retail



Toshinobu Iwasaki, Ph.D. Corporate Officer, Senior Vice President, Corporate Quality Management Division

# Promoting the Shionogi Product Policy and "Quality Culture" worldwide

In July 2015, the Corporate Quality Management Division revised the Shionogi Product Policy and formulated a new Shionogi Group Quality Policy. We did this for two main reasons. First, with Shionogi expanding its business worldwide, we needed a quality policy that complies with global standards. Second, we wanted to overhaul our stance on quality across all activities, from the quality of products themselves to the processes that support them, such as back-office operations, manufacturing and services.

Based on these quality policies, the Corporate Quality Management Division launched new quality assurance initiatives in all areas of manufacturing under the slogan "Quality Culture." In addition to quality assurance in manufacturing processes and document management, we stepped up quality training programs at Shionogi manufacturing sites and contract manufacturing organizations based on our belief that training and education are vitally important to raise awareness of quality control from the bottom up. We are also working closely with overseas subsidiaries (Shionogi Inc., Shionogi Limited) to maintain and enhance quality on a global level, not only in GMP/GDP, but also in other areas of GxP\* such as GCP.

"GxP is a general abbreviation for Good Practice Standards – namely, GLP (Good Laboratory Practice), GMP (Good Manufacturing Practice), GDP (Good Distribution Practice), GCP (Good Clinical Practice), GVP (Good Vigilance Practice) and GPSP (Good Post-marketing Study Practice).

### New drug applications and safety monitoring

We were involved in a large number of new drug applications (NDAs), approvals and product launches in fiscal 2015. Our simultaneous NDAs for *Naldemedine* in Japan and the US was a first for Shionogi. We established a *Naldemedine* global cross-functional team covering Japan, the US and Europe to develop the regulatory strategy and safety data assessment process for the NDAs. Once consensus was reached by the team, we compiled the NDA files, supporting documents and a risk management plan (RMP) and submitted them to the authorities. Shionogi also launched *Actair* and *Cymbalta* was approved for the additional indication of chronic lower back pain. Before these drugs were rolled out, we set up a network with medical institutions and pharmacies to carry out prediction and preventionbased safety monitoring activities after launch. These new post-marketing safety monitoring approaches in Japan are helping to maximize the value of Shionogi products. Also, working with the Human Health Care Division, we plan to proactively provide information to encourage wider use of drug safety information. One example is our plan to build a pharmacoepidemiology research base and use it to develop new methods for using drug information and treatment information with partner organizations.

To achieve our SGS2020 targets, we need to reinforce our domestic business and actively grow our business overseas. As Shionogi's operations become more global, quality risks will increase. The fundamental role of the Corporate Quality Management Division will be to predict, mitigate and eliminate those risks. We will continue to work closely with frontline personnel to ensure the quality of all processes related to Shionogi products.

# **Domestic Business**

# Aiming to be the best medical partner for patients and healthcare professionals



Ryuichi Kume, Ph.D. Executive Officer, Senior Vice President, Human Health Care Division

### **Progress in Fiscal 2015**

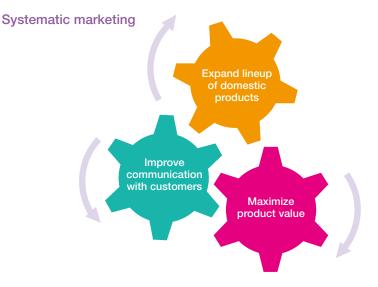
We focused on three strategic products in fiscal 2015: *Crestor, Cymbalta* and the *Irbetan* family of drugs. *Crestor*, which achieved blockbuster status in fiscal 2014, registered further growth, contributing to the treatment of even more patients over the past year. Sales of *Cymbalta* continued to grow, supported by prescriptions for major depressive disorders. We hope more patients will benefit from prescriptions of *Cymbalta* following its approval for the additional indication of chronic low back pain in March 2016. We also added two new drugs to our lineup in fiscal 2015: *Actair* sublingual tablets, an allergen immunotherapy for house-dust mite allergen launched in November 2015, and *Mulpleta* tablets, a Shionogi-developed thrombocytopenia treatment released in December 2015.

We overhauled our operating structure in fiscal 2015 to enable future growth. As part of moves to address changes in our business environment in Japan, the first country in the world to face challenges arising from a rapidly aging society, we are adjusting the strategic focus of the Human Health Care Division. We also established a Medical Relations Unit to respond to expected growth in local healthcare provision. The unit will work with medical representatives to develop healthcare and medical treatment proposals tailored to local needs.

### **Objectives for Fiscal 2016**

We will target resources on *Cymbalta* and *Crestor* in fiscal 2016. *Cymbalta* has a novel mechanism of action as a pain relief agent. We therefore plan to initially focus on providing information about the drug's safety to ensure patients are confident about using *Cymbalta*. We launched *Crestor* orally disintegrating (OD) tablets in June 2016 and we plan to use the new formulation to improve medication adherence\* and enhance the effectiveness of treatment.

Our new Medical Relations Unit will have an increasingly important role to play in advancing community-based healthcare. We will also transfer more authority to each sales area in order to fully leverage our frontline capabilities – one of Shionogi's strengths. Going forward, we will strive to be the best medical partner for patients and healthcare providers while responding to changes in the market positively and taking on new challenges. <sup>\*</sup>A process whereby patients actively participate in decisions on treatment strategies and then receive treatment and medication based on those decisions.



FOCUS ON 03

 $\mathbb{O}^{2}$ 

# Raising awareness

### Promoting antimicrobial stewardship

Infectious diseases, by their nature, are a transmission risk to all people. As borders become more porous and globalization gathers pace, we also face the risk of emerging and re-emerging infectious diseases and antimicrobial resistance – issues that have to be addressed by society as a whole.

At Shionogi, antimicrobial stewardship means selecting the most appropriate antimicrobial agent, dose and administration method and ensuring treatment ends at the optimal time in order to make treatments safe and reliable, control the spread of drug-resistant bacteria and viruses, and support the effective use of healthcare resources. We organize and provide relevant information to promote appropriate use of antimicrobial agents. This involves using antimicrobial susceptibility surveillance programs to gather accurate epidemiological data, rigorously analyzing industry guidelines and improving understanding about pharmaceutical profiles.

Infectious diseases are a threat to human life and can have a major impact on economic activity. Aiming to be the best medical partner for patients and healthcare providers, we are working to counter that threat by providing information about all aspects of infectious diseases, from prevention through to recovery.

### Pain relief management activities

Pain is something we all have to deal with in our lives. Shionogi has established a Pain Management Unit to provide broad support for pain treatment. The unit aims to transform Shionogi into a "pain concierge company." Under this model all Shionogi personnel will work together to provide information and medicines to individual patients for the best pain treatment, which should also encourage more healthcare providers to select Shionogi's products and services.

In fiscal 2015, *Cymbalta* was approved for the additional indications of pain associated with fibromyalgia and chronic low back pain. *Cymbalta* is currently being assessed for the additional indication of pain associated with osteoarthritis and we have submitted an NDA for *Naldemedine* for the treatment of opioid-induced constipation (OIC). We are also seeking approval for an abusedeterrent *OxyContin* formulation and additional indications for *OxyContin* in the area of non-cancer pain.

We therefore have a number of new pain treatmentrelated drugs lined up for approval and launch in fiscal 2016 and beyond. We aim to use these and other products to develop the best possible pain treatment plan for each patient and help relieve the suffering of as many people as possible.



promotes and raises awareness of cancer pain treatments.

# 3 Working closely with healthcare providers

Shionogi's operating environment is undergoing far-reaching change. The Japanese government has launched a community-based healthcare policy and is promoting the creation of a comprehensive local healthcare system and home healthcare services. That means Shionogi will have to address advanced patient and healthcare needs. In October 2015, we established the Medical Relations Unit to build a business model that can contribute to community healthcare. Since its launch, the unit has made contact with prefectural agencies responsible for promoting community healthcare, healthcare providers, healthcare associations and other groups to gather information about the current situation and issues in each area. This information will be used to develop Shionogi's local healthcare activities. The Medical Relations Unit, Distribution Management Department, other related groups inside Shionogi and medical representations will share this information and work together to help resolve issues in community healthcare settings.

# **Global Business Operations**

### Developing global products in the US and upgrading business sites



Masaaki Takeyasu Corporate Officer, Senior Vice President, Global Business Division

### **Progress in Fiscal 2015**

In the US, we have been working to expand sales of postmenopausal vulvar and vaginal atrophy (VVA) treatment *Osphena* (generic name: ospemifene). Our strategy is focused on technical activities to raise awareness among medical professionals about the importance of continuing with *Osphena* for a minimum of 90 days to ensure effectiveness. We are also using DTC\* activities to influence consultation behavior and are channeling significant resources into increasing health insurance coverage for *Osphena* treatments. In the second half of fiscal 2015, we launched a purchasing support scheme to reduce the out-of-pocket cost for patients, based on conditions in their private health insurance plans. This drove a clear upturn in prescriptions, with *Osphena* currently the only drug to register sales growth in the sluggish US market for VVA treatments. We also steadily rolled out ospemifene in Europe, launching it under the *Senshio* brand name in Italy in October 2015 and Spain in January 2016. We are now working to secure approval for ospemifene in Singapore. Our Chinese subsidiary, C&O Pharmaceutical Technology (Holdings) Limited, is currently building a business base to transform itself into a highly profitable company through the launch of new drugs.

Taiwan Shionogi & Co., Ltd. has established a dedicated division to promote the appropriate use of infectious disease treatments in order to address the serious global public health issue of drug-resistant bacteria, and Beijing Shionogi Pharmaceutical Technology Limited has created a similar organization to actively tackle the issue in Asia.

### **Objectives for Fiscal 2016**

In the US, one of our priority markets in SGS2020, we plan to expand sales of *Osphena* by implementing highly targeted sales strategies for each regional market based on sales performance to date. We will also put in place structures to drive rapid sales growth for *Naldemedine* after launch, which is scheduled for fiscal 2017.

In Europe, we will continue to develop new drugs and promote *Senshio*. In Asia, we will implement initiatives to promote the appropriate use of infectious disease treatments and make preparations to launch new products.

### Ospemifene – a global product

We launched ospemifene (brand name: *Osphena*) in the US in June 2013 as the world's first oral treatment for VVA. Until that point, VVA was treated using topical estrogen-based treatments. The drug has been approved to treat physiological changes in the vaginal epithelium and for moderate to severe symptoms of dyspareunia due to menopause. People suffering from dyspareunia are reluctant to talk about their condition, which can have a serious impact on relationships. By working to truly understand these concerns, we will continue to implement marketing activities that encourage as many people as possible to at least give the treatment a try. Our TV commercials for *Osphena* feature real patients talking about their actual experiences to help raise awareness of the symptoms. In Italy and Spain, we have launched ospemifene as *Senshio*, also for the treatment of moderate to severe symptoms of dyspareunia. We plan to roll out ospemifene as our first global development product in other markets worldwide.



FOCUS ON 04



### Maximizing our strengths

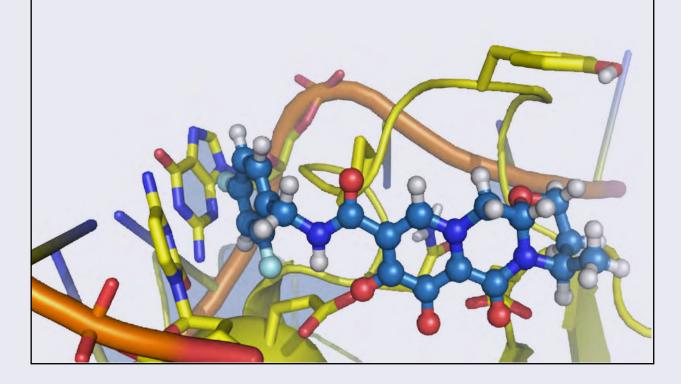
# Aiming to grow as a drug discovery-based pharmaceutical company

We launched SGS2020 with the aim of "growing as a drug discovery-based pharmaceutical company," focusing on the two core therapeutic areas of infectious diseases and pain / CNS disorders. Our decision to focus on those two fields reflects our long track record of developing drugs to treat infections and pain.

Infectious diseases are an inseparable part of the human condition and have affected people since the dawn of time. With Alexander Fleming's discovery of penicillin in 1928, we finally gained a tool to control infections. Since then, it has been a constant battle to develop drugs that are effective against various pathogens, which then build up resistance to survive, requiring renewed efforts to discover effective new medicines. Shionogi has played an important role in the global fight against infections, including emerging infectious diseases and the resurgence of existing diseases. This is a Shionogi strength that we have to maintain and develop further.

In pain and CNS disorders, demand for treatments is rising worldwide as societies age rapidly. New drugs and other improvements in healthcare have helped to extend average life expectancy around the world. Now attention is turning to ways of using healthcare to increase healthy life expectancy from the perspective of QOL. Pain and deteriorating cognitive functions can have a major negative impact on QOL. By providing drugs that extend healthy life expectancy, we can make life better for many people.

To achieve that objective, we are leveraging our strengths in small-molecule drug development to create accessible and affordable medicines in our two core therapeutic fields of infectious diseases and pain / CNS disorders. Collaborating with other companies and external research bodies will be crucial to achieve one of our core principles – to supply the best possible medicine to protect the health and wellbeing of the patients we serve. Strong alliances are built on the best possible partners using the best possible methods to maximize innovation. That thinking is behind our efforts to reinforce Shionogi's presence through partnerships with pharmaceutical companies and academic centers of excellence in Japan and overseas.



### Domestic Sales of Prescription Drugs in Fiscal 2015

## Prescription Drugs Major Products

Shionogi will work steadily to expand its share in the Japanese market, focusing on seven strategic products.

### Crestor® tablets Crestor® OD tablets

(hyperlipidemia treatment) Crestor® tablets launched April 2005

Crestor® OD tablets launched June 2016

Shionogi-developed statin therapy *Crestor* has been proven highly effective in lowering LDL cholesterol and is a leader among dyslipidemia treatments in Japan and overseas. It reduces the risk of atherosclerotic diseases, and affords physicians and patients a greater sense of satisfaction and reliance. *Crestor OD* tablets were developed using Shionogi technology to improve patient adherence. The tablets are hard yet disintegrate rapidly.

### Cymbalta<sup>®</sup> Capsules

(Treatment for depression, depressive condition, diabetic neuropathic pain, fibromyalgia pain and chronic lower back pain) Launched April 2010

 algia pain and chronic lower back pain)

 Launched April 2010

 Cymbalta is a serotonin and noradrenaline reuptake inhibitor

 approved as an anti-depressant in more than 100 countries.

approved as an anti-depressant in more than 100 countries. It is recommended as the first-line treatment for diabetic neuropathic pain (DNP) in domestic and international guidelines.

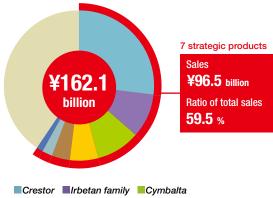
*Cymbalta* received approval in Japan for the additional indication of pain associated with fibromyalgia in May 2015 and for the additional indication of pain associated with chronic lower back pain in March 2016.

### Irbetan family of drugs Irbetan<sup>®</sup> Tablets AIMIX<sup>®</sup> Combination Tablets IRTRA<sup>®</sup> Combination Tablets (Antihypertensive)



Irbetan® Tablets launched July 2008, AIMIX® Combination Tablets launched December 2012, IRTRA® Combination Tablets launched September 2013

*Irbetan* is a long-acting angiotensin II receptor blocker (ARB) with a powerful hypotensive effect lasting 24 hours and anti-metabolic organ protecting effects. Shionogi also sells the drug as part of combination formulations, such as *AMIX* Combination Tablets with calcium antagonist amlodipine, and *IRTRA* Combination Tablets with diuretic trichlormethiazide, contributing to the treatment of hypertension through a family of *Irbetan* products.



OxyContin family Pirespa Finibax

Rapiacta Other prescription drugs

### OxyContin family of drugs OxyContin® Tablets OxiNorm® Powder OxiFast® Injection (Cancer pain analgesic)

OxyContin<sup>®</sup> tablets launched July 2003, Oxi/Norm<sup>®</sup> powder launched February 2007, OxiFast<sup>®</sup> injection launched May 2012

A combination of 12-hour sustained-release *OxyContin* tablet and immediate-release *OxiNorm* powder enables cancer pain to be relieved more effectively.

*OxiFast* injection can be used for pain relief in patients with difficulty taking oral drugs.

### Pirespa® Tablets

(Idiopathic pulmonary fibrosis treatment)

*Pirespa* is the world's first drug to be indicated for idiopathic pulmonary fibrosis.

*Pirespa* is expected to inhibit the decrease in vital capacity and slow the progression of idiopathic pulmonary fibrosis.

### Finibax® for Intravenous Drip Infusion Finibax® solution kit for Intravenous Drip Infusion (Carbapenem-type antibiotic)



Launched September 2005 (kit: launched June 2006)

Shionogi-developed *Finibax* is a carbapenem-type antibiotic for injection with strong antibacterial activity against *Pseudomonas aeruginosa*.

There is increasing expectation surrounding this product's effectiveness as a treatment for serious and intractable infections such as sepsis, pneumonia, and peritonitis.

### Rapiacta<sup>®</sup> for Intravenous Drip Infusion (Antiviral drug for influenza)



Launched January 2010

*Rapiacta* is the world's first neuraminidase inhibitor for intravenous drip infusion. As a single-dose intravenous drip infusion, *Rapiacta* can be expected to produce reliable treatment benefits, enabling it to be used to treat outpatients and hospitalized patients in all age groups, from infants to the elderly.



# Shionogi Healthcare established

We established Shionogi Healthcare Co., Ltd. as a wholly owned subsidiary in January 2016 to provide consumer healthcare products in Japan.

#### Reasons for setting up Shionogi Healthcare

As the world's first country to face the challenges of a rapidly aging society, Japan needs to curb public healthcare expenditures, which totaled more than ¥40 trillion in fiscal 2013. The government is promoting self-medication as part of a package of measures to reduce health-care spending. Over-the-counter (OTC) drugs are set to play a key role in this approach, includ-ing preferential tax treatment for OTC drug purchases from fiscal 2017. This is likely to lead to far-reaching changes in the healthcare environment in Japan. Against this backdrop, Shionogi Healthcare's mission is to help extend healthy life expectancy by contributing to patient health in the field of self-medication, which will bring us into closer contact with the end-users of our products.

#### An independent, dynamic company

In the OTC drugs category, where consumers have the final say about which products to buy, market needs move and change all the time. Companies have to constantly stay abreast of that change by rapidly developing new products, securing marketing approval and adjusting sales promotion strategies. Responding to that kind of change on a daily business is difficult for any single business division in Shionogi, but a standalone company is more nimble, offering a sig-



Itaru Hirano Shionogi Healthcare President & Chief Executive Officer

nificant competitive advantage. We believe an independent company will give us a better chance of success in the selfmedication market.

#### Strategic products

Shionogi Healthcare focuses on four categories – pain, oral care, health support and infections. Oral care in particular is a promising growth market. Over the last decade, as seniors have become healthier, there has been a dramatic increase in the number of people retaining their principal natural teeth. However, at the same time, there are still many people who lose interest in food after losing some of their teeth in old age. Our *Correct* Series of denture adhesives, which includes three distinctive types of adhesive – cushion, stick-on and tape-type – improves the stability of dentures, making talking more fun and helping to maintain and improve appetite. The *Correct* Series is one of the brands in our portfolio that can make a real difference to healthy life expectancy.

#### A presence in all areas of the value chain - development, manufacturing and selling

Shionogi Healthcare will adhere to the Company Policy of Shionogi and work to develop, manufacture and sell OTC drugs in an integrated and efficient way, aiming to continually evolve as a company that helps extend the healthy life expectancy of as many people as possible.

### Key products

Analgesics Sedes Series



Fast-acting, effective analgesics with isopropylantipyrine for the treatment of intolerable pain. Multivitamin supplements Popon Series



A lineup of pharmaceutical-grade multivitamins for people prone to poor health.





Isodine® contains povidone-iodine, a powerful antiseptic that was taken on the Apollo moon mission. It can be used as a mouthwash, ointment and handwash. Shionogi began selling Isodine® in 2016 after signing an exclusive sales collaboration contract with Mundipharma. Isodine® is globally known as Betadine® brand.

Isodine® is a registered trademark of Mundipharma K.K.

### **Corporate Governance**

# All the Company's directors are committed to supporting sustained growth and increasing corporate value over the medium and long term.



Back row from left: Keiichi Ando, Takuko Sawada, Akio Nomura, Teppei Mogi Front row from left: Motozo Shiono, Isao Teshirogi, Ph.D.

#### **Fundamental Policy**

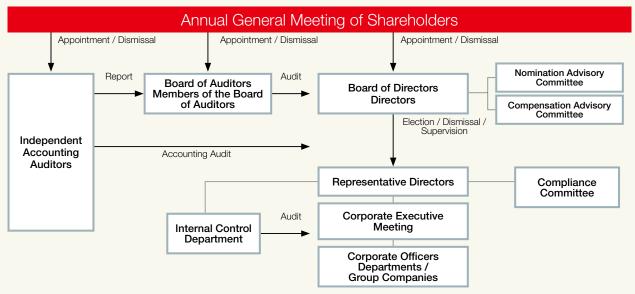
The Shionogi Group has created a corporate governance structure to make its Company Policy – the Group's corporate philosophy – a reality worldwide. In accordance with the spirit of Japan's Corporate Governance Code, which came into effect in 2015, the Group defines corporate governance as a structure 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 Board of Directors has formulated the Group's Basic Views and Guidelines on Corporate Governance to realize the best possible corporate governance.

In accordance with the Group's Basic Views and Guidelines on Corporate Governance, the Shionogi Group will fulfill its fiduciary responsibility to shareholders and its obligations to all stakeholders in order to deliver sustained growth and increase corporate value over the medium and long term.

#### **Corporate Governance Structure**

The Shionogi Group 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 our 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.

#### Corporate Governance Structure (As of June 30, 2016)



#### **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 management decisions are equitable, 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.

#### Audit Framework

To ensure 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 the 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 and Composition of Advisory Committees**

#### Nomination Advisory Committee

The Nomination Advisory Committee supports the Board of Directors in an advisory role. The committee is chaired by an outside director and is tasked with assessing the suitability of candidates for the position of director in a fair and equitable manner.

#### **Compensation Advisory Committee**

The Compensation Advisory Committee is also an advisory body for the Board of Directors. The committee is chaired by an outside director and assesses appropriate levels of compensation for directors in accordance with their duties.

		Nomination Advisory Committee	Compensation Advisory Committee
	Motozo Shiono	•	
Directors	Isao Teshirogi, Ph.D.	•	•
	Takuko Sawada		
	Akio Nomura	Chairperson	•
Outside Directors	Teppei Mogi	•	Chairperson
	Keiichi Ando		
Corpo-	Akira Okamoto		•
rate Auditors	Ikuo Kato		
Outside	Shinichi Yokoyama		
Corpo- rate	Kenji Fukuda		
Auditors	Koichi Tsukihara		

Committee Members

# Our Response to the Corporate Governance Code (extracts)

#### General Principle 1

Securing the Rights and Equal Treatment of Shareholders

#### Policy

The Company substantively ensures shareholder rights at the General Meeting of Shareholders, including voting rights, and maintains an environment in which all shareholders are able to properly exercise their rights as shareholders.

#### Initiatives

- The Company held its Annual General Meeting of Shareholders on June 23, avoiding June 29 when many other companies hold their shareholder meetings.
- The Company sent out a Notice of Convocation for the Annual General Meeting of Shareholders three weeks before the meeting (June 1) and posted the notice on its website six days before sending it out (May 26).
- Photos and reasons for selecting each director and auditor candidate were included in the convocation documents.
- The Company maintains an environment that facilitates the electronic exercise of voting rights, which includes the use of the ICJ Electronic Voting Platform<sup>\*1</sup>. An English translation of the Notice of Convocation was disclosed on the Company's website and via TDnet<sup>\*2</sup> and the ICJ website.
- \*1: Operated by ICJ Incorporated, a joint venture between the Tokyo Stock Exchanged and Broadridge Financial Solutions, Inc.
- \*2: Timely Disclosure network: A system operated by the Tokyo Stock Exchange that provides listed companies with a platform
- to make material corporate information widely available in a swift and timely manner.

# General Principle 3 Ensuring Appropriate Information Disclosure and Transparency

#### Policy

As a company widely trusted by society, the Group believes that improving management transparency is an important obligation. This belief is the basis for our Disclosure Policy, which calls for the Group to continuously disclose appropriate company information fairly and at the proper time to all stakeholders.

#### Initiatives

- The Company disclosed its corporate philosophy and medium-term management plan.
- The Company formulated and disclosed the Group's Basic Views and Guidelines on Corporate Governance.
- The Company disclosed the policy and procedures for determining director pay.
- The Company disclosed the policy, procedures and specific reasons for selecting director candidates.

#### General Principle 4

#### Responsibilities of the Board

#### Policy

#### Framework

To enhance business oversight by directors, improve management transparency, and promote highly equitable management, the Company will nominate candidates for directors in accordance with the following guidelines:

- Outside (independent) directors shall account for half or greater than half of the board.
- Various aspects including management experience, specialized knowledge in areas including law and finance,
- and medical and pharmaceutical viewpoints shall be considered.
- Ensuring diversity in terms of gender, age, nationality and expertise shall be considered.

In appointing outside independent directors, the Company shall select candidates based on standards for independency set by Financial Instrument Exchanges and the Requirements and Independence Standards the Company has set for outside independent directors to fulfill their roles and responsibilities.

#### **Roles and responsibilities**

The directors (Board of Directors) shall fulfill the crucial role and obligation of supervising decisions regarding important matters that affect management and business execution.

Matters that require decisions by the Board of Directors are defined by resolutions in the rules governing the board. Responsibility for decisions about important matters not covered by resolutions in those rules shall be delegated to the management team, primarily to executive officers.

#### Support structure for directors and auditors

Directors and auditors are provided information required for the fulfillment of their roles and obligations in a timely manner, and information requested by directors and auditors is provided to them by the Company. In addition, the Company has put in place a system that provides staffing and financial support to directors and auditors.

#### Initiatives

- The Company worked to improve cooperation between outside directors and outside auditors and between outside directors, outside auditors and senior management through various meetings, including meetings between the president to exchange opinions, and meetings and seminars organized by standing auditors to share opinions with and learn from senior management.
- The Company conducted a survey of directors and auditors and held separate meetings with them to analyze and evaluate the effectiveness of the Board of Directors in 2015. The evaluation focused on systems, roles, responsibilities and operational matters related to directors and the Board of Directors, in accordance with the Group's Basic Views and Guidelines on Corporate Governance.

The evaluation process confirmed that the Board of Directors is operating in an appropriate and effective manner. Based on the results of the evaluation, the Company plans to make ongoing improvements to further enhance the effectiveness of the Board of Directors.

General Principle 5

#### **Dialogue with Shareholders**

#### Investor Relations that Address Equity Market Needs

As part of its investor relations activities, the Shionogi Group actively discloses useful information that meets the needs of the equity market. At press conferences and conference calls, senior managers clearly explain the Group's management policy and earnings performance and provide more detailed information at smaller investor meetings. Shionogi also holds an annual briefing on research and development, and explains progress in target therapeutic areas.

Going forward, we intend to continue communicating closely with shareholders and other investors, reflecting their opinions and advice in our operations to increase corporate value.

#### **Shionogi Receives Best IR Award**

The Japan Investor Relations Association (JIRA) presents its IR Prime Business Awards each year to companies that have actively taken steps leading to significant achievements in IR, including strong support from market participants, underpinned by a deep understanding of the purposes of IR. All publicly listed JIRA member companies are eligible for the awards. Shionogi received the Best IR Award in 2015 and the IR Special Award in 2014.

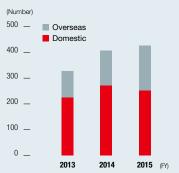
#### Reasons Shionogi was selected for the Best IR Award:

- Senior management is committed to IR activities and its explanations are persuasive.
- Relevant investor opinions are reflected in business management and IR activities are used to create corporate value.
- The Company makes genuine efforts to disclose information and senior management also explains negative information related to earnings.
- Personnel involved in drug development regularly hold R&D briefings, helping to raise internal awareness about the importance of information disclosure.

#### Ranked Top in the Best IR Company Category by Institutional Investor Magazine

Institutional Investor, a leading US financial magazine known worldwide, has compiled a list of Japan's leading companies for IR activities, based on the votes of 570 international institutional investors and analysts. In the All-Japan Executive Team Rankings, Shionogi was selected as the Best IR Company and Isao Teshirogi was voted the Best CEO in the healthcare & pharmaceuticals industry. These rankings helped Shionogi secure the Most Honored Company position in the healthcare & pharmaceuticals industry.

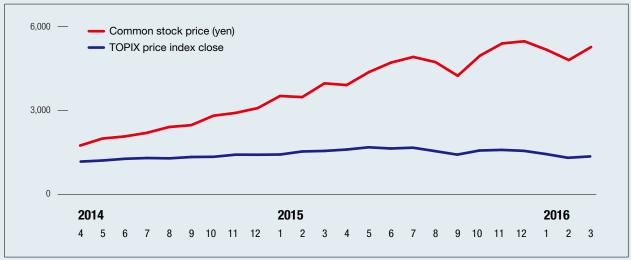
Number of meetings with institutional investors and securities analysts







### Stock Price (Tokyo Stock Exchange)



Please read our Corporate Governance Report for more detailed disclosures and information required by the Corporate Governance Code.

#### Internal Control System – Basic View and Current Status

In May 2006, the Board of Directors passed a resolution adopting a Basic Policy for Building an Internal Control System to ensure appropriate business operations. Since then, the entire Shionogi Group has worked to improve the system. Based on the system's current status, the Board of Directors reviews the content of the original resolution each year in order to continually strengthen and enhance the system and its operation.

To address internal control system reporting requirements in the Financial Instruments and Exchange Act, we are working to raise awareness and promote the importance of reliable financial reporting across the Group's operations worldwide. In addition, we carefully evaluate our System for Ensuring the Adequacy of Documents on Financial Calculation and of Other Information, making incremental improvements each year to improve the reliability of financial reporting across the Group.

The Company Policy of Shionogi is both our corporate philosophy and our corporate values. We are promoting transparent and honest management by sharing this policy with all senior managers and employees and ensuring they strictly adhere to its principles.

#### **Risk Management**

For major risks that could have a particularly large impact on the Group's operations, such as natural disasters, accidents and corporate scandals, the Shionogi Group follows the Compendium for countermeasures against such risks and BCP (Business continuity plan) Guidelines based on its Crisis Management Standard, implementing crisis management processes that emphasize respect for human life, consideration and support for local communities and mitigation of damage to corporate value. The Group also identifies underlying risk factors in each of its organizational units and formulates response strategies to avoid or mitigate those risks.

In order to achieve the goals of SGS2020 and maintain the Group's growth, Shionogi recognizes the importance of building a solid management base to protect its business assets. The Group is therefore working to increase physical security levels across all its operations. Every Shionogi employee endeavors to protect the Group's valuable business assets, based on a constant and high level of risk awareness.

#### **Protecting Intellectual Property**

Intellectual property is an extremely important business asset for pharmaceutical companies. Under our intellectual property strategy, we protect various innovations, such as drug compounds, use application, 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 the Group'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, taking all legal means necessary if the Group's intellectual properties appears to have been infringed.

#### **Rigorous Compliance**

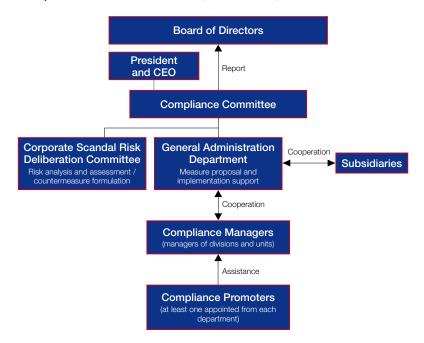
To continue growing as a global company in the pharmaceutical field, Shionogi must be an honest company with a strong set of moral values.

We have published the Shionogi Group Compliance Policy internally and externally and all employees are required to put the policy into practice to increase awareness about the importance of compliance. We have also formulated the Shionogi Code of Practice and published a clear Shionogi Group Anti-Corruption / Anti-bribery Policy.

To educate executives and Group employees about compliance, we prepare and distribute the Shionogi Compliance Handbook, disseminate messages and reminders about compliance and conduct surveys to understand employee attitudes to compliance.

All employees rigorously adhere to our compliance policies and always act in an honest manner in order to support the Group's growth and earn the respect of society.

#### Compliance Promotion Structure (As of March 2016)



### **Messages from Outside Directors**

Companies have to secure public trust and sustainably develop based on that trust in order to make a meaningful contribution to society. Strengthening corporate governance is an indispensable part of that process. In concrete terms, that means ensuring decision-making is transparent and actively disclosing information to stakeholders.

Shionogi's Board of Directors has taken a positive stance on reinforcing corporate governance and has worked to improve management transparency and quality.

Drawing on my experience in business management and knowledge acquired in the Kansai business community, I will continue to emphasize my independence as an outside director while working to further enhance the transparency and quality of management at Shionogi.



As Shionogi grows as a global drug discovery-based pharmaceutical company, I will provide the necessary legal guidance and advice to support that process and help the Group, including overseas subsidiaries, reinforce corporate governance and compliance structures. In this way, I intend to use my legal expertise to contribute to fair and principled decision-making at Shionogi.



Teppei Mogi Outside Director

Outside Director

My name is Keiichi Ando, Shionogi's newly appointed outside director.

I have a wide range of experience in the field of finance. Also, in my role as CEO of NEW KANSAI INTERNATIONAL AIRPORT COMPANY, LTD I have led the development and implementation of the company's Strategic Growth Program, overhauled its business model and successfully transformed Kansai International Airport into Japan's first privately operated airport.

Using this experience and expertise to the full, I intend to provide sound advice to Shionogi to help it realize its SGS2020 vision of growing as a drug discovery-based pharmaceutical company, aiming to contribute to the Group's growth and improvements in business management.



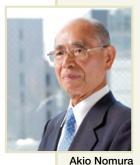
Keiichi Ando Outside Director

### Message from New Standing Member of the Board of Auditors

Amid dramatic change in the operating environment, Shionogi will need to invest heavily in new drug development and form global alliances in order to generate organic, sustainable growth as a drug discovery-based pharmaceutical company, ensuring it retains public trust. To achieve this, management will need to make some major business decisions that entail risk. As a standing member of the Board of Auditors, I will draw on my experience and knowledge from the frontline of drug discovery research to ensure risks taken by the management team are within acceptable parameters and are likely to contribute to growth in corporate value. I will do my best to ensure all our stakeholders retain trust in Shionogi as a drug discovery-based pharmaceutical company.



Ikuo Kato Standing Member of the Board of Auditors



# Members of Boards (As of June 30, 2016)

#### Directors



Motozo Shiono Chairman of the Board and Representative Director

#### 1972 Joined the Company

- 1984 General Manager, Marketing Planning Department
- 1984 Director of the Company
- 1987 General Manager, Accounting Department
- 1987 Managing Director of the Company 1990 Senior Managing Director of the Company
- 1996 General Manager, Agro., Vet. & Industrial Chem. Division
- 1999 President of the Company
- 1999 General Manager, Corporate Planning Division
- 2008 Chairman of the Board (incumbent)

Attended all 11 Board of Directors' meetings



Isao Teshirogi, Ph.D. President and CEO

#### 1982 Joined the Company

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

Attended all 11 Board of Directors' meetings



#### Takuko Sawada

Director of the Board, Senior Executive Officer, Senior Vice President, Corporate Strategy Division

- 1977 Joined the Company
- 2002 Executive General Manager, Pharmaceutical Development Division
- 2007 Officer and Executive General Manager, Pharmaceuti-cal Development Division
- 2010 Executive Officer and Executive General Manager, Pharmaceutical Development Division
- 2011 Senior Executive Officer and Executive General Manager, Global Development Office 2013 Senior Executive Officer and Senior Vice President,
- Global Development Office and Pharmaceutical Development Division
- 2014 Senior Executive Officer and Senior Vice President, Global Pharmaceutical Development Division
- 2015 Director of the Company, Senior Executive Officer and Senior Vice President, Corporate Strategy Division (incumbent)

Attended all 9 Board of Directors' meetings

#### **Outside Directors**



Akio Nomura Outside Director

1998 Representative Director and President, Osaka Gas, Co., Ltd.

- 2000 Director, West Japan Railway Company 2003 Representative Director and Chairman,
- Osaka Gas, Co., Ltd.
- 2008 Outside Director, Royal Hotel, Ltd. (incumbent) 2009 Outside Director of the Company (incumbent)

Attended all 11 Board of Directors' meetings

#### Significant Concurrent Position

Outside Director, Royal Hotel, Ltd.



Teppei Mogi Outside Director

- 1989 Registration as attorney at law
- 1989 Joined Oh-Ebashi Law Offices 1994 Partner, Oh-Ebashi Law Offices (incumbent)
- 2002 Partner, Oh-Ebashi LPC & Partners (incumbent)
- 2004 Professor, Kwansei Gakuin University Law School
- 2005 Part-time instructor, Kobe University Graduate School of Law
- 2009 Outside Director of the Company (incumbent) 2010 Part-time instructor, Kwansei Gakuin University Law School (incumbent)
- 2014 Outside Corporate Auditor, Niitaka Co., Ltd. 2015 Outside Corporate Auditor of KURABO INDUSTRIES LTD.
- 2015 Outside Director (Audit & Supervisory Committee member) of NIITAKA Co., Ltd. (incumbent)
- 2016 Outside Director (Audit & Supervisory Committee member) of KURABO INDUSTRIES LTD, (incumbent)

Attended all 11 Board of Directors' meetings

#### Significant Concurrent Positions

Partner, Oh-Ebashi Law Offices Partner, Oh-Ebashi LPC & Partners Outside Director (Audit & Supervisory Committee member) of NIITAKA Co., Ltd Outside Director (Audit & Supervisory Committee member) of KURABO INDUSTRIES LTD.



- 2003 Executive Officer, Sumitomo Mitsui Banking Corporation
- 2006 Managing Executive Officer, Sumitomo Mitsui Banking Corporation
- 2009 Director and Senior Managing Executive Officer, Sumitomo Mitsui Banking Corporation
- 2010 Representative Director and Deputy President and Executive Officer, Sumitomo Mitsui Banking Corporation
- 2012 Representative Director and President, NEW KANSAI INTERNATIONAL AIRPORT COMPANY, LTD
- 2012 Representative Director and President and CEO. NEW KANSAI INTERNATIONAL AIRPORT COMPANY, I TD
- 2016 Outside Director of the Company (incumbent) 2016 Representative Director and President, Ginsen Co., Ltd. (incumbent)

#### Significant Concurrent Position

Representative Director and President, Ginsen Co., Ltd.

- Keiichi Ando Outside Director

### Standing Members of the Board of Auditors



Akira Okamoto Standing Member of the Board of Auditors

1978 Joined the Company

- 2006 General Manager, Business Support Center 2007 General Manager, General Affairs & Personnel
- Department 2008 General Manager, Human Resources Department
- 2011 General Manager, Internal Control Department
- 2015 Standing Member of the Board of Auditors of the

Company (incumbent)

Attended all 9 Board of Directors' meetings Attended all 6 Board of Auditors' meetings



Ikuo Kato Standing Member of the Board of Auditors

#### 1988 Joined the Company

- 2007 General Manager, Development Research Laboratories2010 General Manager, Drug Development Research
- Laboratories
- 2011 General Manager, Drug Development Research Laboratories and Representative Director and President, Shionogi TechnoAdvance Research & Co., Ltd
- 2013 General Manager, Drug Development Research Laboratories and Representative Director and Chairman, Shionogi TechnoAdvance Research & Co., Ltd
- 2014 Representative Director and Chairman, Shionogi TechnoAdvance Research & Co., Ltd
   2016 Standing Member of the Board of Auditors of the
- Company (incumbent)

#### **Corporate Officers**

Senior Executive Officer Takuko Sawada

### Executive Officers

Takuo Fukuda Ryuichi Kume, Ph.D. Yoshiaki Kamoya Takayuki Yoshioka, Ph.D.

#### Corporate Officers

Kohji Hanasaki, Ph.D. Masaaki Takeyasu John Keller, Ph.D. Kazuhiro Hatanaka Miyuki Hiura Toshinobu Iwasaki, Ph.D. Takeshi Shiota, Ph.D.

#### Outside Members of the Board of Auditors



Shinichi Yokoyama Outside Member of the Board of Auditors

- 2001 President, Sumitomo Life Insurance Company
- 2003 Outside Corporate Auditor, NEC Corporation 2007 Chairman and Representative Director, Sumitomo Life
- Insurance Company 2008 Outside Member of the Board of Auditors of the Company (incumbent)
- 2010 Outside Corporate Auditor, Sumitomo Chemical Co., Ltd. (incumbent)
- 2014 Director, Corporate Advisor, Sumitomo Life Insurance Company
- 2014 Outside Corporate Auditor, Rengo Co., Ltd. (incumbent)
- 2014 Retired as Director and Corporate Advisor, Sumitomo Life Insurance Company

Attended all 11 Board of Directors' meetings Attended all 8 Board of Auditors' meetings

#### Significant Concurrent Positions

Outside Corporate Auditor, Sumitomo Chemical Co., Ltd.

Outside Corporate Auditor, Rengo Co., Ltd.



Kenji Fukuda Outside Member of the Board of Auditors

1984 Registration as attorney at law 1984 Joined Dojima Law Office

- 1987 Partner, Dojima Law Office (incumbent) 2009 Vice President, Osaka Bar Association
- 2009 Governor, Japan Federation of Bar Associations
- 2009 Visiting Professor, Osaka University Law School
- 2011 Outside Member of the Board of Auditors of the Company (incumbent)

#### Significant Concurrent Positions

Partner, Dojima Law Office



Koichi Tsukihara Outside Member of the Board of Auditors

- 2005 Deputy President and Executive Officer, Sumitomo Mitsui Banking Corporation
- 2005 Vice President and Executive Managing Officer, Sumitomo Mitsui Financial Group 2006 Representative Director and President, Sumitomo
- Mitsui Card Co., Ltd.
- 2011 Representative Director and Chairman, Sumitomo Mitsui Card Co., Ltd.
- 2012 Director and Chairman, Sumitomo Mitsui Card Co., Ltd.
- 2012 Outside Director, Gurunavi, Inc. (incumbent)2013 Outside Member of the Board of Auditors of the Company (incumbent)

Attended all 11 Board of Directors' meetings Attended all 8 Board of Auditors' meetings

#### Significant Concurrent Positions

Outside Director, Gurunavi, Inc.

# A Diverse Relationship with Society

Shionogi has spent many years building strong relationships of trust with various stakeholder groups.

The Shionogi Group's basic policy is "to strive constantly to supply the best possible medicine to protect the health and wellbeing of the patients we serve." In line with this goal, we have actively worked as a member of society to help create a sustainable, healthy society by implementing a program of social initiatives, in addition to the contribution we make through our business activities.

Since Shionogi was founded in 1878 through to the present day, the Shionogi Group has implemented various initiatives to protect health and wellbeing.

Our overriding goal has been to supply medicines to people in need. We have also helped enhance healthcare and promote healthier lifestyles by developing new drugs, which give healthcare professionals more treatment options for the patients they serve.

Our stakeholders are not limited to patients and healthcare professionals. To protect health and wellbeing, we need to improve the quality of healthcare and medical care. That means relying on different people in the healthcare field and improving their knowledge and technical skills. Also, advanced healthcare is only made possible by advanced science. That's why we also believe it is important to support groundbreaking research in Japan and overseas, and the people involved in that research.

Improving accessibility to advanced healthcare is also key. Healthcare by itself does not protect health and wellbeing. We also therefore have to increase understanding of public health issues and raise awareness about the accessibility of health services, while also putting in place systems that make it easier to access those services. Similarly, we need to improve access to healthcare in developing countries, where systems and infrastructure are not as reliable as in advanced countries. Educating the public about the correct use of medication is another increasingly important area.

As a pharmaceutical company, we have a role to play in driving sustained improvement in the quality of healthcare and protecting health and wellbeing by supplying products, services and opportunities that bring together various groups in the healthcare sector. This is how the Shionogi Group can fulfill its responsibility to society.

# Protecting health and wellbeing

#### **Contributing through** medicine

• Supplying the best possible medicines to patients in need

• Research, produce and promote

#### Contributing through advances in science and healthcare

• Supporting groundbreaking research • Training researchers

 Promoting proper use of medicines • Improving public health in develop-

Contributing through

better access

to healthcare

ing countries

From Japan to Africa

# Our people are vital to Shionogi's sustainability and innovation



# Contributing through advances in science and healthcare

#### Shionogi-affiliated foundations that promote science and healthcare

Established in 1915, the Research Foundation Itsuu Laboratory conducts a broad range of pharmaceutical research, focusing mainly on advanced synthetic organic chemistry research themes such as the total synthesis of natural alkaloids. The foundation also supports young researchers. Similarly, the Hoansha Foundation, established in 1954, has helped advance pharmaceutical research by providing grants for research and studies in the field of pharmaceutical science. We also established the Cell Science Research Foundation in 1988, recognizing the potential of cell science at a time when the field was still in its infancy. By providing grants for research and support for researchers, the foundation has played a key role in pushing forward developments in the field of cell science. Through these foundations, Shionogi has made a significant contribution to advances in science and healthcare in Japan over many years.

#### Shionogi joints the Milner Therapeutics Institute and Consortium

The Milner Therapeutics Institute and Consortium (MTC), based at the University of Cambridge in the UK, was established in 2015 to focus on drug discovery research. The consortium connects three academic centers of excellence in medical and biological research (Cambridge University, Babraham Institute, Sanger Institute) with four pharmaceutical companies (Shion-ogi, Astex, AstraZeneca, GSK) to share their respective expertise and unique resources in collaborative research projects that accelerate the discovery of better medicines. Shionogi is the only consortium member with its head office outside the UK.

In addition to specific collaborative projects, MTC aims to create and enhance innovative drug discovery technologies and actively use them to plan and implement pre-competitive drug research. One part of that approach is the Grand Challenge system launched in 2016. Under this system, academic scientists bring their advanced drug discovery ideas to MTC, which then plans and supports their further development.

By participating in this innovative consortium, we aim to realize the main goal of our Company Policy worldwide – to strive constantly to supply the best possible medicine to protect the health and wellbeing of the patients we serve.

#### Contributing to the GHIT Fund

#### (Global Health Innovative Technology Fund)

Antibiotics have saved millions of people from the threat of dangerous pathogens. However, we are now seeing rapid growth in microbes and infections such as tuberculosis and malaria that have acquired resistance to many modern drug treatments. At the same time, the development of effective new antibiotic treatments that can counter drug-resistant bacteria has stalled. Neglected tropical diseases (NTDs) also remain a threat to the lives of many people in developing countries amid limited progress in developing effective antibiotics. One reason for this lack of progress is that many pharmaceutical companies have withdrawn from infectious disease research due to poor prospects for substantial profits.

Against this backdrop, many funds are being set up worldwide to advance research into new antibiotics. In Japan, the not-for-profit GHIT Fund has been established to promote collaboration with overseas partners and provide research funding. Shionogi has been a contributor to the GHIT Fund since it was founded and has received funding to advance the discovery of new drugs that can treat multidrug-resistant tuberculosis. Under the auspices of the fund, Shionogi is also actively working to eliminate the threat of infectious diseases in general, such as taking part in a program to search for new antibiotics.

We aim to step up our role in the global fight against multidrug-resistant bacteria through international collaboration, illustrated by our commitment to a joint declaration calling for greater cooperation at the World Economic Forum in Davos in January 2016.

#### **Sponsor of Music Fair**

We have been the sole sponsor of the TV music program Music Fair since it first aired in Japan in August 1964.

Our goal has been to give as many people as possible the opportunity to relax with music through a TV program that features the best artists performing songs in a great atmosphere with the highest quality sound, lighting and sets.



# Contributing through better access to healthcare

### Mother to Mother SHIONOGI Project launched

We launched the Mother to Mother SHIONOGI Project in October 2015 as part of our efforts to protect the health and wellbeing of people worldwide.

Under this project, we are supporting the health of mothers and children in both Japan and Kenya through sales of our Popon Series of multivitamin supplements, popular for many years in the domestic market. Mothers in Japan who use Popon gain health benefits, while a portion of product sales and contributions from Shionogi employees are donated to a program that improves the health of mothers and children in Kenya. The program is run by World Vision International, a global NGO.

Despite its vast size, Kenya has few medical clinics, which makes it difficult for expectant mothers to receive regular prenatal checkups, give birth in a clinical setting and return home healthy with their newborn child, which we take for granted in Japan.

Our donations have so far contributed to the construction of a local medical clinic and health network in the traditional lands of the Maasai people, helping to improve the health of local people by improving access to healthcare. Through the program, we are also working to improve the autonomy of community healthcare systems by providing training for local staff in the Maasai tribal areas.

# People are key to Shionogi's future and innovation —

### Promoting diversity management

At Shionogi, we believe companies need to continuously innovate in order to make a sustained contribution to society. The diverse values and ideas of employees are crucial to this continuous innovation and employees need a safe and healthy working environment to help them remain motivated on a daily basis. We are implementing a range of measures that emphasize this link. These measures have been rated highly by various external groups.

### Chosen for the New Diversity Management Selection 100 project

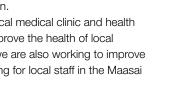
Shionogi was selected by Japan's Ministry of Economy, Trade and Industry (METI) for the New Diversity Management Selection 100 project, which recognizes companies that develop innovative ideas by harnessing diverse talent in their business, including women, people from overseas, the elderly and people with disabilities. Shionogi was recognized for efforts by the Human Health Care Division to actively draw on the unique perspective of female employees in its business activities.

### Shionogi certified as a leading company for women by the City of Osaka

The City of Osaka has established a certification system to recognize companies that actively promote the empowerment of women in the workplace, such as creating structures to ensure women remain motivated and providing support for work-life balance. Shionogi was awarded the highest level of certification - businesses that have set up the necessary systems and achieved tangible results. Shionogi was recognized for systems that help female employees balance work and home life and that address long working hours.

### Selected as a Health & Productivity Stock

The Health & Productivity Stock selection program is part of measures in the Japanese government's Japan Revitalization Strategy aimed at extending the healthy life expectancy of Japanese people. Under the program, METI and the Tokyo Stock Exchange (TSE) select TSE-listed companies that are leaders in health and productivity management and are working to improve corporate value from a long-term perspective. The goal is to encourage companies to step up health and productivity management activities. Shionogi was selected for the 2016 list due to our efforts in a range of areas, such as initiatives to reduce the employee smoking rate to zero, walking events and the use of health insurance claim data to mitigate deterioration in employee health.











# **Respecting the Environment**



Yoshiaki Kamoya Executive Officer

#### EHS policy and Shionogi's business activities

To remain sustainable, companies need to address today's global environmental issues, as well as concerns about health and safety. In October 2015, we released the Shionogi Group EHS\* Policy. Based on this policy, we are working to create safe workplaces and build a better society through business activities that take into account issues such as protecting the global environment, preventing pollution, and ensuring safe and healthy workplaces and communities for everyone. Through this policy, which covers EHS activities in the Shionogi Group and across its supply chain, we aim to support sustainable business development.

\*EHS: Environment, health and safety

#### EHS Unit and system to promote EHS

We established the EHS Unit in April 2016 to realize the Shionogi Group EHS Policy worldwide. The unit is tasked with multiple roles, such as building a Companywide EHS management system, developing a common Shionogi strategy for addressing various EHS-related issues, and assessing whether business activities are being conducted in an appropriate manner at Shionogi and in related supply chains (audits). In recent years, overseas manufacturers have been conducting EHS audits in addition to quality assurance audits. In a global business context, EHS initiatives are increasingly seen as integral to ensuring stable supplies of pharmaceuticals. With the help of related business divisions, the Shionogi Group has started work on building an EHS audit system. By advancing EHS-related initiatives, the EHS Unit will work to create safe workplaces and help build a better society, while also supporting the Group's operations.

#### Initiatives at the Kanegasaki Plant

At the Kanegasaki Plant, we have taken a number of steps to reduce  $CO_2$  emissions, such as shifting to a liquefied natural gas (LNG)-fired boiler and installing a cogeneration power system. As a result, the plant was awarded the highest 4-star ranking in Iwate Prefecture's certification system for eco-friendly business facilities. Initiatives at the plant also helped us achieve our 2020 target for  $CO_2$  emissions in the Shionogi Group Environmental Protection Plan five years early.



#### **Initiatives to Reduce Environmental Impact**

We have adopted biomass bottles (bio-polyethylene bottles) for *Cymbalta* capsules. Biomass bottles are pharmaceutical packaging containers made from polyethylene derived from materials leftover in sugarcane processing. By switching from conventional bottles made from



petroleum-derived polyethylene, we are helping to reduce CO<sub>2</sub> emissions and conserve fossil fuel resources.

Biomass plastic identification labeling on *Cymbalta* packaging

Biomass bottles are compliant with biomass plastic identification labeling standards set by the Japan BioPlastics Association, as they contain more than 90% sugarcane-derived polyethylene.

#### Initiatives at the Aburahi Botanical Gardens

Since its establishment in 1947, Aburahi Botanical Gardens has conducted research into medicinal plants and protected plant species. Today, Aburahi Botanical Gardens is actively involved in protecting medicinal plants unique to Shiga Prefecture, where the facility is located, including rare plants such as endangered and near-threatened species.

Aburahi employees also work with staff at medical plant gardens at Kyoto Pharmaceutical University and Kobe Pharmaceutical University to support science and environmental education. Our employees have helped a local elementary school create a medicinal herb farm on the school grounds and show the children how to use herbs from the gardens to make indigo and purple dyes. They also run hands-on classes about medicinal plants at the botanical gardens.





Amsonia elliptica (Japanese Bluestar), a near-threatened plant species

#### Phase 4 of the Shionogi Group Environmental Protection Plan and Results

We have worked to reduce the Group's total environmental impact by implementing initiatives under Phase 4 of the Shionogi Group Environmental Protection Plan (fiscal 2011 to fiscal 2015). During Phase 4, conditions within the Group changed significantly, including the consolidation of research facilities and the construction of new buildings. Despite these changes, the Group largely achieved its Phase 4 targets. The results of activities during Phase 4 of the Shionogi Group Environmental Protection Plan are shown below. From fiscal 2016, we will continue our efforts to reduce  $CO_2$  emissions and industrial waste in line with new targets in Phase 5 of the Shionogi Group Environmental Protection Plan, which has been formulated based on current industry targets and other assumptions.

Targets	Environmental Protection Plan Targets	and Results
<ul> <li>Promote measures to conserve energy and counter global warming</li> <li>Reduce CO<sub>2</sub> emissions by 23% compared with the fiscal 2005 benchmark year (fiscal 2020)</li> <li>Reduce the specific energy consumption by an annual average of 1%</li> <li>Promote the introduction of highly energy-efficient equipment and facilities</li> </ul>	Measures to conserve energy and counter global warming At the Kanegasaki Plant, energy supply facilities were converted to LNG and a cogeneration power system was installed. Boiler fuel conversions were also carried out at the Aburahi Facilities and Shionogi Pharma Chemicals Co., Ltd., and all business sites reviewed the operation of air conditioning systems, installed high-efficiency transformers and heat pumps and switched to LED lights in office areas. Compared with the benchmark year, CO <sub>2</sub> emissions were reduced by 27%. Average annual specific energy consumption improved 2.4%.	Benchmark       95,679       100         Fiscal Year Actual       92,558       95,4         PY2012 Actual       82,155       88,4         FY2013 Actual       83,927       97,2         FY2014 Actual       68,194       95,679         FY2015 Actual       69,420       85,7         Target Fiscal Year <sup>1</sup> 73,673       94,1         CO2 emissions (tons)       95,6679       94,1         Fiscal year targets: fiscal 2020 for emission volumes, fiscal 2015 for the Specific energy consumption       94,1         * Specific energy consumption       * Specific energy consumption       * Specific energy usage (crude oil basis) by total floor area
<ul> <li>Strengthen conservation of resources and waste disposal measures</li> <li>Reduce the amount of waste generated by 10% compared with the fiscal 2010 benchmark year (20% reduction by fiscal 2020)</li> <li>Promote zero emissions</li> </ul>	Conservation of resources and waste disposal measures We continued to improve manufacturing processes, recover valuable materials from waste liquids and waste plastic, and cut the volume of waste liquids and other materials through the application of the 3Rs: reduce, reuse and recycle. Compared with the bench- mark year, the amount of waste generated was reduced by 20%. The landfill disposal rate was 2.5%.	Benchmark     4,961     2.0       FY2011 Actual     4,744     2.7       FY2012 Actual     4,275     2.0       FY2013 Actual     4,275     2.0       FY2014 Actual     3,509     2.0       FY2015 Actual     3,944     2.0       FY2015 Actual     3,944     2.0       FY2015 Target     4,442     1.0       FY2020 Target     3,986     ≦1.0       ■ Waste generated (tons)     – Landfill disposal rate (%)
<ul> <li>Strengthen management of chemical substances</li> <li>Reduce atmospheric emissions of dichloromethane in the manufacture of active pharmaceutical ingredients (APIs) by 45% compared with the fiscal 2010 benchmark year</li> <li>Control the use and atmospheric emission of chemical substances</li> <li>Promote the proper treatment and management of polychlorinated biphenyls (PCBs)</li> </ul>	Management of chemical substances The Kanegasaki Plant continued to reduce atmospheric emissions of dichloromethane. The treatment of equipment with high levels of PCB contamination was completed in fiscal 2013. We are currently formulating a schedule for the complete disposal of equipment and ballast with low levels of PCB contamination. We are also responding to the Revised Fluorocarbons Recovery and Destruction Law, which came into effect in April 2015.	Benchmark       114         Fiscal Year Actual       89         FY2011 Actual       89         FY2012 Actual       101         FY2013 Actual       65         FY2014 Actual       43         FY2015 Actual       54         FY2015 Target       63         Image: Atmospheric emissions of dichloromethane at the Kanegasaki Plant (tons)
<ul> <li>Promote understanding of biodiversity</li> <li>Properly preserve and increase endangered plant species in the Company's botanical gardens</li> <li>Conduct education on biodiversity and related laws and regulations</li> </ul>	the Aburahi Facilities. We also used visual trainin conducted training at the research division about	· · · · · · · · · · · · · · · · · · ·
<ul> <li>Promote the introduction of low-emission vehicles</li> <li>Allocate hybrid or electric vehicles for 93% of cars lent to medical representatives (except in cold regions)</li> </ul>	Introduction of low-emission vehicles Hybrid vehicles now account for 93% of all vehicles leased to MRs.	FY2010 Actual       40         FY2011 Actual       49         FY2012 Actual       80         FY2013 Actual       91         FY2014 Actual       91         FY2015 Actual       93         FY2015 Target       93

#### Third-party Opinion

To improve the reliability and transparency of our environmental activity disclosures, we have asked two experts from the Institute for Environmental Management Accounting (IEMA), Professor Dr. Katsuhiko Kokubu and Eriko Nashioka, to assess our environmental stance and environmental management status and provide advice about future activities.

Ratio of EVs and HVs (%)

### **11-Year Performance Highlights**

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.

	2006	2007	2008	2009	
For the years ended March 31:					
Net sales	¥196,389	¥199,759	¥214,268	¥227,512	
Cost of sales	68,708	67,542	68,594	70,929	
Selling, general and administrative expenses	98,455	103,354	105,275	124,568	
Operating income	29,226	28,863	40,399	32,015	
Profit before income taxes	38,798	31,723	39,963	30,786	
Profit attributable to owners of parent	22,735	18,595	25,064	15,661	
Net cash provided by operating activities	16,885	14,116	15,619	29,120	
Net cash used in investing activities	(12,048)	(8,418)	(5,336)	(149,056)	
Net cash used in financing activities	(24,796)	(7,181)	(17,124)	105,294	
Research and development expenses	32,257	37,456	40,290	52,822	
Capital investments	11,132	11,107	13,069	10,875	
Depreciation and amortization	8,653	8,798	10,666	13,468	
As of March 31:					
Property, plant and equipment, net	¥ 64,251	¥ 67.815	¥ 70,378	¥ 71,812	
Total assets	427,683	429,569	413.704	501,853	
Total long-term liabilities	38,371	36,282	29,024	114,955	
Total net assets	337,434	345,752	342,236	310,094	
Per share amounts:					
Profit attributable to owners of parent	¥ 66.55	¥ 54.61	¥ 74.21	¥ 46.75	
Net assets	989.76	1,014.73	1,020.31	924.43	
Dividends	16.00	16.00	22.00	28.00	
Other:					
Equity ratio	78.8	80.4	82.7	61.7	
Return on equity [ROE]	7.1	5.4	7.3	4.8	
Payout ratio	24.0	29.3	29.6	59.9	
Non-Financial Data:					
Employees (Number)	4,997	4,958	4,982	6,010	
CO2 emissions (Thousand tons – CO2)*1	_	_	_	_	
Amount of waste generated (t)	_	_	_	—	
Ratio of hybrid and electric vehicles (%)*2	_	_	_		

\*1 The electric power CO<sub>2</sub> conversion uses internally specified figures. Data are from the fiscal year ended March 31, 2010 because of a change to the scope of aggregation following enforcement of the Amended Act on Temporary Measures for Promotion of Rational Uses of Energy and Recycled Resources in 2010.

\*2 Excludes cold regions of Japan Notes:

1. U.S. dollar figures have been calculated, for convenience only, at the rate of ¥112.62 = US\$1.00, the approximate rate of exchange on March 31, 2016.

2. From the fiscal year ended March 31, 2007, the Company has adopted a new accounting standard for the presentation of net assets in the balance sheet, which reclassifies former shareholders' equity, valuation and translation adjustments, and minority interests as total net assets. Figures for fiscal years through the year ended March 31, 2006 have been calculated in conformity with the new standard.

S. From the first all 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.

#### 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 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 

	ss operations	overnent of busine	Continueu impro				
2016	2016	2015	2014	2013	2012	2011	2010
Thousands of U.S. dollars	Millions of yen						
\$2,752,380	¥309,973	¥273,991	¥289,717	¥282,904	¥267,275	¥282,350	¥278,503
663,808	74,758	82,190	77,993	78,575	77,753	81,737	76,264
1,276,940	143,809	141,437	149,849	144,764	142,519	153,721	149,801
811,632	91,406	50,364	61,875	59,565	47,003	46,892	52,438
865,326	97,453	82,052	63,188	58,307	41,495	33,135	58,541
592,142	66,687	44,060	40,618	66,728	27,102	20,027	38,626
908,276	102,290	45,604	79,496	59,276	54,724	56,528	52,902
(292,089)	(32,895)	(31,697)	(20,040)	(19,960)	(38,290)	(13,947)	(826)
(164,491)	(18,525)	(46,211)	(53,799)	(37,687)	(27,749)	(27,011)	(4,979)
442,088	49,788	48,870	53,606	53,021	53,599	50,921	51,808
88,288	9,943	8,163	8,962	11,447	13,233	17,967	12,547
111,694	12,579	12,673	12,913	11,912	16,282	17,966	18,048
Thousands of U.S. dollars	Millions of yen						
\$ 698,579	¥ 78,674	¥ 77,023	¥ 78,977	¥ 78,474	¥ 74,282	¥ 70,221	¥ 62,448
5,679,622	639,639	602,900	580,566	574,882	522,162	523,242	540,762
477,526	53,779	56,222	33,721	53,042	92,900	115,326	131,956
4,562,929	513,877	478,883	467,836	423,633	347,198	328,096	341,976
U.S. dollars	Yen						
\$1.82	¥ 204.83	¥ 132.67	¥ 121.29	¥ 199.25	¥ 80.93	¥ 59.80	¥ 115.33
13.89	1,564.73	1,456.70	1,385.11	1,254.44	1,027.83	979.69	1,019.71
0.55	62.00	52.00	46.00	42.00	40.00	40.00	36.00
	% <b>70</b> C	70 7	70.0	70 1		00.7	CO 0
	79.6	78.7	79.9	73.1	65.9	62.7	63.2
	13.6 30.3	9.4	9.2	17.5	8.1	6.0	11.9
	30.3	39.2	37.9	21.1	49.4	66.9	31.2
	5,896	6,059	6,165	6,082	6,132	5,277	5,887
	69	68	84	89	93	87	104
	3,944	3,509	4,275	4,564	4,744	4,961	6,218
	93	91	91	80	49	40	
		01	01	00	40	40	

### **Management's Discussion and Analysis**



Kohji Hanasaki, Ph.D. Corporate Officer Vice President, Finance & Accounting Department

**Net Sales** 

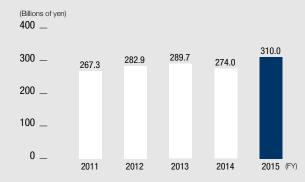
#### Message from the Head of the Finance & Accounting Department

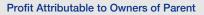
In fiscal 2015, ended March 31, 2016, we reported net sales of ¥310.0 billion, ahead of our sales target, and operating income of ¥91.4 billion and exceeding the previous record levels of 2014. Royalty income of ¥40.5 billion from ViiV Healthcare Ltd. made a significant contribution to profits, reflecting strong sales growth for anti-HIV agent *Tivicay* and combination drug *Triumeq*, which have been outlicensed to ViiV Healthcare.

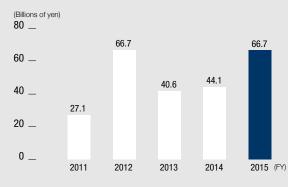
One of our management goals at Shionogi is to build an operating structure that does not rely on royalty income. We made good progress towards this goal in fiscal 2015, reporting operating income of ¥3.3 billion excluding royalties from *Crestor* and HIV franchise products. We will work to end our dependence on royalty income by generating further top-line growth in fiscal 2016 and beyond.

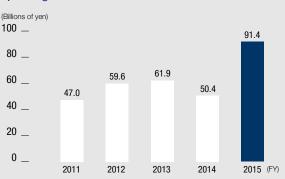
There was also significant improvement in the cost of sales ratio, from 30.0% in fiscal 2014 to 24.1% in the year under review. This was achieved by strategically reviewing contracts and purchasing terms with domestic and overseas suppliers and by optimizing logistics, which helped to lower our cost base. We also reinforced cost control by ensuring resources were strategically allocated in line with clear priorities.

Going forward, we will continue to work toward our profit targets while increasing Shionogi's market presence by securing approval for and launching new development compounds in the core therapeutic areas of infectious diseases and pain / CNS disorders. We will also target further sales growth in domestic and overseas businesses.

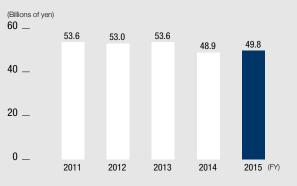








**R&D** Expenses



### Operating Income

### **Net Sales and Profits**

#### **Net Sales**

Net sales rose 13.1% year on year to ¥309,973 million.

#### 1. Domestic Sales of Prescription Drugs

Sales of prescription drugs in Japan increased 0.4% year on year to ¥162,104 million.

Sales of the Company's eight strategic products, centered on three new drugs – hyperlipidemia treatment *Crestor*, hypertension treatment *Irbetan* and antidepressant and pain medication *Cymbalta* – increased 3.8% to ¥99,405 million, outstripping a drop in sales from long-listed drugs and contributing to sales growth overall.

#### 2. Exports and Overseas Subsidiaries

Sales from exports and overseas subsidiaries rose 3.6% year on year to ¥29,711 million.

In the US business, postmenopausal vulvar and vaginal atrophy (VVA) treatment *Osphena* was the only drug to register sales growth in the shrinking VVA market. To maximize the value of *Osphena* in the US, we have started Phase III trials for additional indications. In Europe, we launched sales of the drug under the *Senshio* name in Italy, which is facing issues related to an aging society.

#### 3. Royalty Income

Total royalty income increased 67.8% year on year to ¥101,842 million.

ViiV Healthcare reported global sales of more than £1.3 billion (roughly ¥230 billion) from anti-HIV agent *Tivicay* and combination drug *Triumeq*, which have been outlicensed to ViiV Healthcare, resulting in royalty income of ¥40,474 million. Royalty income from *Crestor* also increased 0.4% year on year to ¥47,601 million, partly reflecting a boost from the weak yen.

#### **Gross Profit**

The cost of sales declined 9.0% to ¥74,758 million and the cost of sales ratio improved from 30.0% in fiscal 2014 to 24.1% in the year under review. As a result, gross profit increased 22.6% year on year to ¥235,215 million.

#### Operating Income and Profit Attributable to Owners of Parent

Operating income increased 81.5% year on year to ¥91,406 million, a new record high for Shionogi. Factors supporting profit growth included an improvement in the cost of sales ratio, mainly reflecting changes to the co-marketing arrangement for antidepressant and pain medication *Cymbalta* with Eli Lilly Japan K.K., and more efficient use of selling, general and administrative expenses, including research and development costs.

Profit attributable to owners of parent increased by a strong 51.4% year on year to ¥66,687 million, reflecting growth in operating income and the payment of income taxes for prior fiscal years in fiscal 2014.

#### **Cash Flows**

In fiscal 2015, net cash provided by operating activities totaled ¥102,290 million, an increase of ¥56,686 million compared with the previous fiscal year. This mainly reflected cash provided by an increase in profit before income taxes, a decrease in working capital due to a drop in notes and accounts receivable — trade and affiliates, and an increase in interest and dividends received.

Net cash used in investing activities totaled ¥32,895 million, an increase of ¥1,198 million compared with the previous fiscal year. This mainly reflected cash provided from proceeds from sales and redemptions of short-term investments, offset by cash used for payments into time deposits with terms of longer than three months.

Net cash used in financing activities totaled ¥18,525 million, mainly for cash dividends paid.

As a result, cash and cash equivalents as of March 31, 2016 totaled ¥127,744 million, an increase of ¥49,022 million compared with the end of the previous fiscal year.

#### **Capital Investments**

The Shionogi Group continued to invest in manufacturing, research and development and marketing facilities to increase sales, reduce costs and support the smooth operation of the business in areas such as new product launches and research and development.

In fiscal 2015, capital investment by the Shionogi Group totaled ¥9,943 million, an increase of 21.8% year on year. Spending was mainly focused on manufacturing facilities at the CMC Development Laboratories\* Tokushima Site. Most investment projects were funded from internal sources. There were no sales or disposals of property, plant and equipment during the fiscal year that had a material impact on the Group's manufacturing capabilities.

\* The CMC Development Laboratories were renamed the CMC R&D Division, effective April 1, 2016.

#### Assets, Liabilities and Net Assets

As of March 31, 2016, total assets stood at ¥639,639 million, an increase of ¥36,739 million from the end of the previous fiscal year.

Current assets increased ¥55,663 million from the end of the previous fiscal year, mainly reflecting a decrease in notes and accounts receivable and increases in cash and cash equivalents and short-term investments.

Investments and other assets declined ¥20,575 million from the end of the previous fiscal year, mainly due to the sale of and lower valuations for investments in securities, impairment losses on goodwill and marketing rights and the impact of exchange rates.

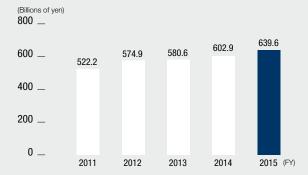
Current liabilities increased ¥4,188 million, primarily due to increases in accrued income taxes and provision for employees' bonuses. Long-term liabilities declined ¥2,443 million, mainly reflecting a drop in deferred tax liabilities due to a decline in the market value of listed stocks.

As of March 31, 2016, total net assets stood at ¥513,877 million, an increase of ¥34,994 million from the end of the previous fiscal year. Shareholders' equity rose ¥48,444 million, reflecting an increase in profit attributable to owners of parent. Total accumulated other comprehensive income declined ¥13,265 million, primarily due to the impact of exchange rates and equity market conditions. Share subscription rights increased ¥82 million to ¥352 million and noncontrolling interests declined ¥267 million to ¥4,086 million.

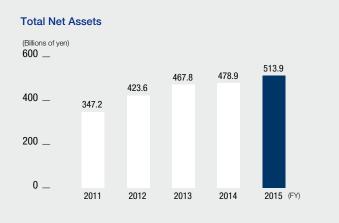
#### **Dividends**

Under Shionogi Growth Strategy 2020 (SGS2020), the Group's Medium-Term Business Plan announced in March 2014, Shionogi is targeting a steady increase in dividends in line with growth, aiming to return profits to shareholders based on a target dividend on equity (DOE) ratio of 3.5% or higher.

Sales of *Tivicay* and *Triumeq* by ViiV Healthcare are growing steadily. Shionogi expects royalties for these drugs and dividends from ViiV Healthcare to support the Group's earnings over the medium and long term. This income also has the potential to make a significant contribution to the Group's growth going forward. The Group's research and development activities are also progressing smoothly and preparations have been made to launch proprietary development compounds worldwide. Given these factors, the Company paid a year-end dividend of ¥34 per share for fiscal 2015. Including the interim dividend, the Company paid a full-year dividend of ¥62 per share, equating to a DOE ratio of 4.1%.



#### Total Assets



### **Business and Other Risks**

The main types of risk that might have a significant impact on the Shionogi Group's management performance and financial condition are listed below.

Forward-looking statements in the text reflect the Group's judgment as of March 31, 2016.

#### (1) 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 the Shionogi Group. In addition, tougher Japanese and overseas regulations in areas such as the development and manufacturing of pharmaceuticals could present the Group with additional expenses or make it difficult for its products to comply with regulations. There is a possibility that this might have an impact on the Group's performance.

#### (2) 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 the Shionogi Group.

#### (3) 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.

#### (4) Intellectual Property Risk

The Shionogi Group 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 the Shionogi Group

#### (5) Risk of Dependence on Certain Products

Crestor product sales and royalty income from Crestor, Tivicay and Triumeg roughly account for a combined 43% of net sales (fiscal year ended March 31, 2016). If an unexpected factor were to cause a drop in or the discontinuation of the sales of one of these products, there is a possibility that this might have an impact on the Group's performance.

#### (6) Risk of Alliances with Other Companies

The Shionogi Group engages in diverse forms of alliances with other companies with respect to joint research, joint research, development and marketing, and other activities, including 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 on the Group's performance.

#### (7) Risk of Natural Disasters or Pandemics

The sudden occurrence of natural disasters or other unforeseen incidents or a pandemic could lead to the closure of plants, laboratories or other business sites, which could affect the results of the Shionogi Group.

#### (8) 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 the Shionogi Group.

#### (9) Litigation Risk

Through its business activities, the Shionogi Group 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 the Shionogi Group.

#### (10) Other Risks

In addition to the above-listed risks, the Shionogi Group's business activities involve the risks related to regulatory of political and economic factors, and diverse other risks. The above list of risks does not include all the types of risks the Shionogi Group is exposed to.

#### Main Patent Infringement Cases Involving the Shionogi Group

(As of July 25, 2016) Current Status Country / Case Patent / Product Claimant Defendant Court Filing Date European Patent Office Board of Appeal Shionogi patent MSD\*1 Shionogi June 10, 2015 Decision pending Germany / patent infringement action ISENTRESS\*2 Shionogi MSD August 17, 2015 Decision pending Japan / patent infringement action **ISENTRESS** Shionogi MSD August 17, 2015 Decision pending UK / patent invalidation action Shionogi patent MSD Shionogi August 24, 2015 Decision pending Netherlands / patent invalidation Shionogi patent MSD Shionogi October 8, 2015 Decision pending Japan / patent invalidation trial Shionogi patent MSD December 17, 2015 Decision pending Shionogi Germany / compulsory licensing action Shionogi patent ISENTRESS MSD Shionogi January 5, 2016 Decision pending UK / patent infringement action **ISENTRESS** May 23, 2016 Shionogi MSD Decision pending Germany / preliminary injunction for Shionogi patent ISENTRESS MSD Shionogi June 7, 2016 Decision pending compulsory licensing action MSD Netherlands / patent infringement action ISENTRESS Shionogi July 6, 2016 Decision pending

\*1 MSD collectively refers to Merck & Co., Inc., MSD Sharp & Dohme GmbH, their European affiliates, and MSD K.K.

\*2 ISENTRESS is an HIV integrase inhibitor sold by MSD

# **Consolidated Financial Statements**

### **Consolidated Balance Sheet**

March 31, 2016

Millions of yen         (Note 5)           2016         2015         2016           Assets         Current assets:         * 127,744         ¥ 78,722         \$ 1,134,29           Short-term investments (Notes 9 and 14)				Thousands of
Assets       Current assets:       2       2       2       5       1,134,29         Short-term investments (Notes 9 and 14)		Millions	U.S. dollars (Note 5)	
Current assets:       ¥ 127,744       ¥ 78,722       \$ 1,134,29         Short-term investments (Notes 9 and 14)		2016	2015	2016
Cash and cash equivalents (Notes 9 and 14)	Assets			
Short-term investments (Notes 6 and 14)       49,687       30,762       441,19         Notes and accounts receivable (Note 14):       328       457       2,91         Trade       64,880       70,128       576,09         Other       11,309       16,872       100,41         Allowance for doubtful accounts       (45)       (28)       (40)         Inventories (Note 7)       76,472       87,429       679,02         Inventories (Note 7)       42,183       44,482       374,56         Deferred income taxes (Note 13)       13,302       13,539       118,11         Other current assets       6,223       5,014       55,255         Total current assets       315,611       259,948       2,802,44         Property, plant and equipment:       8,408       8,410       74,655         Buildings and structures.       114,978       113,007       1,020,93         Machinery, equipment and vehicles (Note 10)       80,516       79,537       714,93         Furniture and fixtures.       37,520       36,971       333,15         Construction in progress.       7,872       5,416       69,89         Accumulated depreciation.       (170,620)       (166,318)       (1,515,00)	Current assets:			
Notes and accounts receivable (Note 14):         328         457         2,91           Affiliates         64,880         70,128         576,09           Other         11,309         16,872         100,41           Allowance for doubtful accounts         (45)         (28)         (40)           Inventories (Note 7)         87,429         679,02         679,02           Inventories (Note 7)         42,183         44,482         374,56           Deferred income taxes (Note 13)         13,302         13,539         118,11           Other current assets         6,223         5,014         55,255           Total current assets         315,611         259,948         2,802,44           Property, plant and equipment:         8,408         8,410         74,655           Buildings and structures         114,978         113,007         1,020,933           Machinery, equipment and vehicles (Note 10)         80,516         79,537         714,933           Furniture and fixtures         37,520         36,971         333,15           Construction in progress         7,872         5,416         69,898           Accumulated depreciation         (170,620)         (166,318)         (1,515,00)	Cash and cash equivalents (Notes 9 and 14)	¥ 127,744	¥ 78,722	\$ 1,134,292
Affiliates       328       457       2,91         Trade       64,880       70,128       576,09         Other       11,309       16,872       100,41         Allowance for doubtful accounts       (45)       (28)       (40)         Inventories (Note 7)       42,183       44,482       374,56         Deferred income taxes (Note 13)       13,302       13,539       118,11         Other current assets       6,223       5,014       55,25         Total current assets       315,611       259,948       2,802,44         Property, plant and equipment:       8,408       8,410       74,65         Buildings and structures       114,978       113,007       1,020,93         Machinery, equipment and vehicles (Note 10)       80,516       79,537       714,93         Furniture and fixtures       37,520       36,971       333,15         Construction in progress       7,872       5,416       69,89         Accumulated depreciation       (170,620)       (166,318)       (1,515,00)	Short-term investments (Notes 6 and 14)	49,687	30,762	441,192
Trade       64,880       70,128       576,09         Other       11,309       16,872       100,41         Allowance for doubtful accounts       (45)       (28)       (40         76,472       87,429       679,02         Inventories (Note 7)       42,183       44,482       374,56         Deferred income taxes (Note 13)       13,302       13,539       118,11         Other current assets       6,223       5,014       55,25         Total current assets       315,611       259,948       2,802,44         Property, plant and equipment:       8,408       8,410       74,655         Buildings and structures       114,978       113,007       1,020,93         Machinery, equipment and vehicles (Note 10)       80,516       79,537       714,93         Furniture and fixtures       37,520       36,971       333,15         Construction in progress       7,872       5,416       69,89         Accumulated depreciation       (170,620)       (166,318)       (1,515,00)	Notes and accounts receivable (Note 14):			
Other.         11,309         16,872         100,41           Allowance for doubtful accounts.         (45)         (28)         (40           76,472         87,429         679,02           Inventories (Note 7)         42,183         44,482         374,56           Deferred income taxes (Note 13)         13,302         13,539         118,11           Other current assets         6,223         5,014         55,25           Total current assets         315,611         259,948         2,802,44           Property, plant and equipment:         8,408         8,410         74,655           Buildings and structures.         114,978         113,007         1,020,93           Machinery, equipment and vehicles (Note 10)         80,516         79,537         714,93           Furniture and fixtures.         37,520         36,971         333,15           Construction in progress.         7,872         5,416         69,89           Accumulated depreciation.         (170,620)         (166,318)         (1,515,00)	Affiliates	328	457	2,913
Allowance for doubtful accounts.         (45)         (28)         (40           Inventories (Note 7)         76,472         87,429         679,02           Inventories (Note 7)         42,183         44,482         374,56           Deferred income taxes (Note 13)         13,302         13,539         118,11           Other current assets         6,223         5,014         55,25           Total current assets         315,611         259,948         2,802,44           Property, plant and equipment:         8,408         8,410         74,65           Buildings and structures         114,978         113,007         1,020,93           Machinery, equipment and vehicles (Note 10)         80,516         79,537         714,93           Furniture and fixtures         37,520         36,971         333,15           Construction in progress         7,872         5,416         69,89           Accumulated depreciation         (170,620)         (166,318)         (1,515,00)	Trade	64,880	70,128	576,097
76,472         87,429         679,02           Inventories (Note 7)         42,183         44,482         374,56           Deferred income taxes (Note 13)         13,302         13,539         118,11           Other current assets         6,223         5,014         55,25           Total current assets         315,611         259,948         2,802,44           Property, plant and equipment:         8,408         8,410         74,65           Buildings and structures         114,978         113,007         1,020,93           Machinery, equipment and vehicles (Note 10)         80,516         79,537         714,93           Furniture and fixtures         37,520         36,971         333,15           Construction in progress         7,872         5,416         69,89           Accumulated depreciation         (1,515,00)         (166,318)         (1,515,00)	Other	11,309	16,872	100,417
Inventories (Note 7)	Allowance for doubtful accounts	(45)	(28)	(400)
Deferred income taxes (Note 13)       13,302       13,539       118,11         Other current assets       6,223       5,014       55,25         Total current assets       315,611       259,948       2,802,44         Property, plant and equipment:       8,408       8,410       74,65         Buildings and structures.       114,978       113,007       1,020,93         Machinery, equipment and vehicles (Note 10)       80,516       79,537       714,93         Furniture and fixtures.       37,520       36,971       333,15         Construction in progress       7,872       5,416       69,89         Accumulated depreciation.       (170,620)       (166,318)       (1,515,00)		76,472	87,429	679,027
Deferred income taxes (Note 13)         13,302         13,539         118,11           Other current assets         6,223         5,014         55,25           Total current assets         315,611         259,948         2,802,44           Property, plant and equipment:         8,408         8,410         74,65           Buildings and structures.         114,978         113,007         1,020,93           Machinery, equipment and vehicles (Note 10)         80,516         79,537         714,93           Furniture and fixtures.         37,520         36,971         333,15           Construction in progress         7,872         5,416         69,89           Accumulated depreciation.         (170,620)         (166,318)         (1,515,00)	Inventories (Note 7)	42,183	44,482	374,560
Other current assets         6,223         5,014         55,25           Total current assets         315,611         259,948         2,802,44           Property, plant and equipment:         8,408         8,410         74,65           Buildings and structures.         114,978         113,007         1,020,93           Machinery, equipment and vehicles (Note 10).         80,516         79,537         714,93           Furniture and fixtures.         37,520         36,971         333,15           Construction in progress         7,872         5,416         69,89           Accumulated depreciation.         (170,620)         (166,318)         (1,515,00)				118,114
Total current assets       315,611       259,948       2,802,44         Property, plant and equipment:       8,408       8,410       74,65         Land       8,408       8,410       74,65         Buildings and structures       114,978       113,007       1,020,93         Machinery, equipment and vehicles (Note 10)       80,516       79,537       714,93         Furniture and fixtures       37,520       36,971       333,15         Construction in progress       7,872       5,416       69,89         Accumulated depreciation       (170,620)       (166,318)       (1,515,00)	Other current assets			55,257
Property, plant and equipment:       8,408       8,410       74,65         Land       8,408       8,410       74,65         Buildings and structures.       114,978       113,007       1,020,93         Machinery, equipment and vehicles (Note 10).       80,516       79,537       714,93         Furniture and fixtures.       37,520       36,971       333,15         Construction in progress.       7,872       5,416       69,89         Accumulated depreciation.       (170,620)       (166,318)       (1,515,00)	Total current assets	ř		2,802,442
Land       8,408       8,410       74,65         Buildings and structures       114,978       113,007       1,020,93         Machinery, equipment and vehicles (Note 10)       80,516       79,537       714,93         Furniture and fixtures       37,520       36,971       333,15         Construction in progress       7,872       5,416       69,89         Accumulated depreciation       (170,620)       (166,318)       (1,515,00)				
Land       8,408       8,410       74,65         Buildings and structures       114,978       113,007       1,020,93         Machinery, equipment and vehicles (Note 10)       80,516       79,537       714,93         Furniture and fixtures       37,520       36,971       333,15         Construction in progress       7,872       5,416       69,89         Accumulated depreciation       (170,620)       (166,318)       (1,515,00)				
Land       8,408       8,410       74,65         Buildings and structures       114,978       113,007       1,020,93         Machinery, equipment and vehicles (Note 10)       80,516       79,537       714,93         Furniture and fixtures       37,520       36,971       333,15         Construction in progress       7,872       5,416       69,89         Accumulated depreciation       (170,620)       (166,318)       (1,515,00)				
Land       8,408       8,410       74,65         Buildings and structures       114,978       113,007       1,020,93         Machinery, equipment and vehicles (Note 10)       80,516       79,537       714,93         Furniture and fixtures       37,520       36,971       333,15         Construction in progress       7,872       5,416       69,89         Accumulated depreciation       (170,620)       (166,318)       (1,515,00)	Property plant and equipment:			
Buildings and structures       114,978       113,007       1,020,93         Machinery, equipment and vehicles (Note 10)       80,516       79,537       714,93         Furniture and fixtures       37,520       36,971       333,15         Construction in progress       7,872       5,416       69,89         Accumulated depreciation		0 400	9.410	74 659
Machinery, equipment and vehicles (Note 10)       80,516       79,537       714,93         Furniture and fixtures       37,520       36,971       333,15         Construction in progress       7,872       5,416       69,89         Accumulated depreciation       (170,620)       (166,318)       (1,515,00)			,	-
Furniture and fixtures.       37,520       36,971       333,15         Construction in progress.       7,872       5,416       69,89         Accumulated depreciation.       (170,620)       (166,318)       (1,515,00)	0			
Construction in progress         7,872         5,416         69,89           Accumulated depreciation         (170,620)         (166,318)         (1,515,00)				
Accumulated depreciation				
Property, plant and equipment, net				
	Property, plant and equipment, net	78,674	77,023	698,579
Investments and other assets:	Investments and other assets:			
Investments in securities (Notes 6 and 14) 145,209 157,097 1,289,37	Investments in securities (Notes 6 and 14)	145,209	157,097	1,289,372
		1,816	1,242	16,125
	Asset for retirement benefits (Note 12)	19,664	18,440	174,605
			46,535	365,903
	Marketing rights (Note 8)			233,378
	Long-term prepaid expenses		558	3,658
				45,853
			,	49,707
		````	· · ·	2,178,601
				\$ 5,679,622

	Millions	Thousands of U.S. dollars (Note 5)	
	2016	2015	2016
Liabilities and net assets			
Current liabilities:			
Notes and accounts payable (Note 14):			
Affiliates	¥ 1,209	¥ 731	\$ 10,735
Trade	9,841	10,843	87,382
Construction	4,810	2,187	42,710
Current portion of long-term debt (Notes 11 and 14)	_	39	-
Provision for employees' bonuses	10,119	8,315	89,851
Provision for sales returns	2,414	2,873	21,435
Accrued expenses	14,578	13,371	129,444
Accrued income taxes (Notes 13 and 14)	19,397	16,169	172,234
Deferred income taxes (Note 13)	0	38	0
Other current liabilities (Notes 9 and 11)	9,615	13,229	85,376
Total current liabilities	71,983	67,795	639,167
Long-term liabilities:			
Long-term debt (Notes 11 and 14)	30,074	30,094	267,039
Liability for retirement benefits (Note 12)	9,448	9,901	83,893
Deferred income taxes (Note 13)	12,857	14,538	114,163
Long-term accounts payable — other	279	385	2,477
Other long-term liabilities (Notes 11 and 20)	1,121	1,304	9,954
Total long-term liabilities	53,779	56,222	477,526
Contingent liabilities (Note 16)			
Net assets:			
Shareholders' equity (Note 17):			
Common stock:			
Authorized: 1,000,000,000 shares			
Issued: 351,136,165 shares in 2016 and 2015	21,280	21,280	188,955
Capital surplus	20,227	20,227	179,604
Retained earnings	503,947	455,498	4,474,755
Less treasury stock, at cost	(49,760)	(49,755)	(441,840)
Total shareholders' equity	495,694	447,250	4,401,474
Accumulated other comprehensive income:			
Net unrealized holding gain on securities	26,748	28,675	237,507
Translation adjustments	(7,334)	3,843	(65,122)
Retirement benefit liability adjustments	(5,669)	(5,508)	(50,337)
Total accumulated other comprehensive income, net	13,745	27,010	122,048
Share subscription rights	352	270	3,126
Non-controlling interests	4,086	4,353	36,281
Total net assets (Note 21)	513,877	478,883	4,562,929
Total liabilities and net assets	¥639,639	¥602,900	\$5,679,622

### **Consolidated Statement of Income**

Year ended March 31, 2016

	Millions	of ven	Thousands of U.S. dollars (Note 5)
	2016	2015	2016
Net sales (Notes 18 and 22)	¥309,973	¥273,991	\$2,752,380
Cost of sales (Notes 7 and 18)	74,758	82,190	663,808
Gross profit	235,215	191,801	2,088,572
Selling, general and administrative expenses (Note 18)	143,809	141,437	1,276,940
Operating income	91,406	50,364	811,632
Other income (expenses):			
Interest and dividend income	11,911	22,522	105,763
Interest expense	(208)	(274)	(1,847)
Litigation expenses	(339)	(625)	(3,010)
Exchange (loss) gain, net	(828)	8,094	(7,352)
Gain on sales of investments in securities (Note 6)	3,066	87	27,224
Loss on impairment of marketing rights (Note 8)	(2,583)	_	(22,936)
Litigation settlement (Note 18)	(1,900)	(1,306)	(16,871)
Special retirement benefit expenses (Note 18)	(1,295)	(383)	(11,499)
Loss on devaluation of investments in securities (Note 6)	(705)	_	(6,260)
Gain on sales of property, plant and equipment	_	5,585	_
Gain on business transfer (Note 18)	_	189	_
Other, net	(1,072)	(2,201)	(9,518)
	6,047	31,688	53,694
Profit before income taxes	97,453	82,052	865,326
Income taxes (Note 13):			
Current	28,724	20,820	255,052
Prior period	_	13,544	_
Deferred	2,101	3,469	18,656
	30,825	37,833	273,708
Profit	66,628	44,219	591,618
Profit (loss) attributable to:			
Non-controlling interests	(59)	159	(524)
Owners of parent (Note 21)	¥ 66,687	¥ 44,060	\$ 592,142

### **Consolidated Statement of Comprehensive Income**

Year ended March 31, 2016

	Million	Thousands of U.S. dollars (Note 5)	
	2016	2015	2016
Profit	¥ 66,628	¥44,219	\$ 591,618
Other comprehensive (loss) income:			
Net unrealized holding (loss) gain on securities	(1,927)	3,385	(17,111)
Translation adjustments	(11,385)	10,408	(101,092)
Retirement benefit liability adjustments	(161)	1,080	(1,430)
Other comprehensive (loss) income (Note 19)	(13,473)	14,873	(119,633)
Comprehensive income	¥ 53,155	¥59,092	\$ 471,985
Comprehensive income (loss) attributable to:			
Owners of parent	¥ 53,422	¥58,482	\$ 474,356
Non-controlling interests	(267)	610	(2,371)

# **Consolidated Statement of Changes in Net Assets**

Year ended March 31, 2016

-	Millions of ven					
-	Common stock	Capital surplus	Retained earnings	Treasury stock, at cost	Total shareholders' equity	Net unrealized holding gain on securities
Balance at April 1, 2014, as originally reported	¥21,280	¥20,227	¥429,526	¥(19,756)	¥451,277	¥25,290
Cumulative effect of retrospective application of change in accounting policy	_	_	(2,014)	_	(2,014)	_
Balance at April 1, 2014 as adjusted	21,280	20,227	427,512	(19,756)	449,263	25,290
Profit attributable to owners of parent	_	_	44,060	_	44,060	_
Dividends	_	_	(16,074)	_	(16,074)	_
Purchases of treasury stock	_	_	_	(30,017)	(30,017)	_
Disposal of treasury stock	_	0	_	18	18	_
Other changes	_	_	_	_	_	3,385
Balance at April 1, 2015	21,280	20,227	455,498	(49,755)	447,250	28,675
Profit attributable to owners of parent	_	_	66,687	-	66,687	-
Dividends	_	_	(18,232)	_	(18,232)	_
Purchases of treasury stock	_	_	_	(25)	(25)	_
Disposal of treasury stock	_	(6)	_	20	14	_
Other changes	_	6	(6)	_	_	(1,927)
Balance at March 31, 2016	¥21,280	¥20,227	¥503,947	¥(49,760)	¥495,694	¥26,748

-			Millions	of yen		
-	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, 2014, as originally reported	¥ (6,114)	¥(6,588)	¥ 12,588	¥208	¥3,763	¥467,836
Cumulative effect of retrospective application of change in accounting policy	_	_	_	_	_	(2,014)
Balance at April 1, 2014 as adjusted	(6,114)	(6,588)	12,588	208	3,763	465,822
Profit attributable to owners of parent	_	_	_	_	_	44,060
Dividends	_	_	_	_	_	(16,074)
Purchases of treasury stock	_	_	_	_	_	(30,017)
Disposal of treasury stock	_	_	_	_	_	18
Other changes	9,957	1,080	14,422	62	590	15,074
Balance at April 1, 2015	3,843	(5,508)	27,010	270	4,353	478,883
Profit attributable to owners of parent	-	-	_	-	-	66,687
Dividends	-	-	-	-	-	(18,232)
Purchases of treasury stock	_	_	_	_	_	(25)
Disposal of treasury stock	_					14
Other changes	(11,177)	(161)	(13,265)	82	(267)	(13,450)
Balance at March 31, 2016	¥ (7,334)	¥(5,669)	¥ 13,745	¥352	¥4,086	¥513,877

-	Thousands of U.S. dollars (Note 5)							
-	Common stock	Capital surplus	Retained earnings	Treasury stock, at cost	Total shareholders' equity	Net unrealized holding gain on securities		
Balance at April 1, 2015	\$188,955	\$179,604	\$4,044,557	\$(441,795)	\$3,971,321	\$254,617		
Profit attributable to owners of parent	-	—	592,142	_	592,142	-		
Dividends	-	—	(161,890)	_	(161,890)	-		
Purchases of treasury stock	-	_	-	(222)	(222)	-		
Disposal of treasury stock	-	(54)	_	177	123	-		
Other changes	-	54	(54)	_	_	(17,110)		
Balance at March 31, 2016	\$188,955	\$179,604	\$4,474,755	\$(441,840)	\$4,401,474	\$237,507		

-	Thousands of U.S. dollars (Note 5)						
	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, 2015	\$ 34,123	\$(48,907)	\$ 239,833	\$2,398	\$38,652	\$4,252,204	
Profit attributable to owners of parent	-	-	_	_	-	592,142	
Dividends	-	-	_	-	-	(161,890)	
Purchases of treasury stock	-	-	-	-	-	(222)	
Disposal of treasury stock	-	-	_	-	-	123	
Other changes	(99,245)	(1,430)	(117,785)	728	(2,371)	(119,428)	
Balance at March 31, 2016	\$(65,122)	\$(50,337)	\$ 122,048	\$3,126	\$36,281	\$4,562,929	

### **Consolidated Statement of Cash Flows**

Year ended March 31, 2016

	Millions of yen		Thousands of U.S. dollars (Note 5)
	2016	2015	2016
Operating activities			
Profit before income taxes	¥ 97,453	¥ 82,052	\$ 865,326
Adjustments for:		. ,	
Depreciation and amortization	12,579	12,673	111,694
Loss on impairment of marketing rights	2,583		22,936
Amortization of goodwill	3,291	2,978	29,222
Loss (gain) on sales or disposal of property, plant and equipment, net	282	(4,646)	2,504
Gain on sales of investments in securities	(3,066)	(1,313)	(27,224)
Loss on devaluation of investments in securities	705	(01)	6,260
Gain on business transfer		(189)	
Decrease in liability for retirement benefits	(1,722)	(480)	(15,290)
Interest and dividend income	(11,911)	(22,522)	(105,763)
Interest and dividend income	208	(22,322) 274	1,847
Exchange loss (gain), net	3,632	(7,109)	32,250
Other	(2,167)	21	(19,243)
	(2,107)	21	(13,243)
Changes in operating assets and liabilities: Notes and accounts receivable – trade and affiliates	E 106	(5.750)	46 129
	5,196	(5,752)	46,138
Inventories	1,940	4,701	17,226
Other current assets	908	2,681	8,063
Notes and accounts payable – trade and affiliates	761	530	6,757
Accrued expenses	1,231	(2,365)	10,931
Other current liabilities	1,172	3,469	10,406
Subtotal	113,075	66,229	1,004,040
Interest and dividends received	14,874	9,947	132,073
Interest paid	(192)	(314)	(1,705)
Income taxes paid	(25,467)	(30,258)	(226,132)
Net cash provided by operating activities	102,290	45,604	908,276
Investing activities			
Purchases of short-term investments	¥ (71,288)	¥ (45,529)	\$ (632,996)
Proceeds from sales and redemption of short-term investments	50,218	21,206	445,907
Purchases of investments in securities	(246)	(2,724)	(2,184)
Proceeds from sales of investments in securities	4,022	544	35,713
Purchases of property, plant and equipment	(8,175)	(10,641)	(72,589)
Proceeds from sales of property, plant and equipment	12	8,277	106
Purchases of intangible assets	(6,925)	(2,739)	(61,490)
Purchases of investments in subsidiaries	_	(24)	_
Proceeds from business transfer	_	236	_
Purchases of investments in capital of an affiliate	(543)	_	(4,822)
Other	30	(303)	266
Net cash used in investing activities	(32,895)	(31,697)	(292,089)
-	(,/	(	(,,
Financing activities		(22.222)	(0.07)
Repayment and redemption of long-term debt	(38)	(20,000)	(337)
Proceeds from issuance of bonds	-	20,070	-
Purchases of treasury stock	(25)	(30,051)	(222)
Cash dividends paid	(18,217)	(16,060)	(161,756)
Cash dividends paid to non-controlling interests	—	(20)	—
Other	(245)	(150)	(2,176)
Net cash used in financing activities	(18,525)	(46,211)	(164,491)
Effect of exchange rate changes on cash and cash equivalents	(1,848)	2,688	(16,409)
Net increase (decrease) in cash and cash equivalents	49,022	(29,616)	435,287
Cash and cash equivalents at beginning of year	78,722	108,338	699,005
Cash and cash equivalents at end of year	¥127,744	¥ 78,722	\$1,134,292

#### Notes to Consolidated Financial Statements

March 31, 2016

#### 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 reclassifications of previously reported amounts have been made to conform the consolidated financial statements for the year ended March 31, 2015 to the 2016 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 four affiliates, including TAKATA Pharmaceutical Co., Ltd. for the purpose of the consolidated financial statements for the year ended March 31, 2016 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 eighteen 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. For consolidation purposes, financial statements for this subsidiary are prepared as of and for the year ended December 31. As a result, 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 comprehensible 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 straightline method over their respective estimated useful lives, generally a period of 5 years.

#### (j) Leases

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.

#### (I) 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 gain or loss is 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 gain and loss 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 foreign currency assets, liabilities, 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 foreign currency assets, liabilities, 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 effectiveness of its hedging activities as compared with 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 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 23.)

#### 3. Changes in Accounting Policies

#### (a) Accounting Standard for Business Combinations

Effective April 1, 2015, the Company and its domestic subsidiaries have applied "Accounting Standard for Business Combinations" (Accounting Standards Board of Japan ("ASBJ") Statement No. 21, revised on September 13, 2013), "Accounting Standard for Consolidated Financial Statements" (ASBJ Statement No. 22, revised on September 13, 2013) and "Accounting Standard for Business Divestitures" (ASBJ Statement No. 7, revised on September 13, 2013).

As a result, differences resulting from changes in the Company's ownership interests in subsidiaries are accounted for as changes in capital surplus as long as the parent company retains control over its subsidiaries, and the acquisition related costs are charged to expenses for the period in which they are incurred. Furthermore, for business combinations carried out on or after April 1, 2015, any changes to the allocation of the acquisition cost resulting from the finalization of the provisional accounting treatment are reflected in the consolidated financial statements for the period in which the business combination occurs. In addition, the presentation of net income has been changed, and the presentation of minority interests has been changed to non-controlling interests. Certain accounts in the consolidated financial statements for the year ended March 31, 2015 have been reclassified to reflect the change in presentation.

In the consolidated statement of cash flows, cash flows related to the acquisition or sale of investments in subsidiaries not resulting in changes in the scope of consolidation are to be included in "Financing Activities." In addition, the expenses arising from the acquisition of investments in subsidiaries resulting in changes in the scope of consolidation or cash flows related to expenses arising from the acquisition or sale of investments in subsidiaries not resulting in changes in the scope of consolidation are to be included in "Operating Activities."

"Accounting Standard for Business Combinations" and related guidance were applied in accordance with the transitional treatment provided in Section 58-2 (4) of "Accounting Standard for Business Combinations," Section 44-5 (4) of "Accounting Standard for Consolidated Financial Statements" and Section 57-4 (4) of "Accounting Standard for Business Divestitures," with prospective application of these accounting standards effective from April 1, 2015.

In accordance with the transitional treatment provided in Article 26-4 of the Practical Guidance on Accounting Standard for Preparing Consolidated Statements of Cash Flows, the Company did not reclassify comparative information in the consolidated statement of cash flows for the year ended March 31, 2015.

These changes had no material effect on the consolidated financial statements for the year ended March 31, 2016.

#### (b) Application of Practical Solution on Unification of Accounting Policies Applied to Foreign Subsidiaries for Consolidated Financial Statements

Effective April 1, 2015, the Company has applied "Practical Solution on Unification of Accounting Policies Applied to Foreign Subsidiaries for Consolidated Financial Statements" (Practical Issues Task Force ("PITF") No. 18, revised March 26, 2015). In accordance with the transitional treatment provided in PITF No. 18, Shionogi Inc., which is a subsidiary in the United States, amortizes goodwill for which it has selected amortization treatment based on Topic 350 "Intangibles – Goodwill and Other" of the Financial Accounting Standards Board Accounting Standards Codification over the remaining amortization period of goodwill on its consolidated financial statements.

There was no effect on the consolidated financial statements as a result of this application.

#### 4. Accounting Standards Issued but Not Yet Adopted Implementation Guidance on Recoverability of Deferred Tax Assets (a) Summary

When responsibility for providing practical guidelines on the accounting and auditing treatment of recoverability of deferred tax assets (limited to the portion related to accounting treatment) was transferred from the Japanese Institute of Certified Public Accountants (JICPA) to the ASBJ, the ASBJ partially revised the requirement criteria for entity categorization and the treatment of net deferred tax assets regarding guidance for the recoverability of deferred tax assets mainly prescribed in JICPA Audit Committee Report No. 66 (Auditing Treatment for Determining the Recoverability of Deferred Tax Assets). The ASBJ has mainly adhered to the basic framework for categorization of entities and for estimating the recoverability of deferred tax assets by category. In addition, implementation guidance is described in this guidance for entities adopting Accounting Standard for Tax Effects (Business Accounting Council (Japan)) and assessing deferred tax assets.

- Treatment of companies that do not satisfy any of the category requirements for (Category 1) through (Category 5)
- Category requirements for (Category 2) and (Category 3)
- Treatment related to future deductible temporary differences which cannot be scheduled in companies that qualify as (Category 2)
- Treatment related to the reasonable estimable period of future pre-adjusted taxable income in companies that qualify as (Category 3)
- Treatment in cases that companies that satisfy the category requirements for (Category 4) but qualify as (Category 2) or (Category 3)

#### (b) Scheduled date of adoption

The Company expects to adopt the revised implementation guidance, effective April 1, 2016.

#### (c) Impact of adoption of the implementation guidance

The Company is currently evaluating the effect of adopting this revised implementation guidance on its consolidated financial statements.

#### 5. 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 \$112.62 = U.S.\$1.00, the approximate rate of exchange in effect on March 31, 2016. 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.

# 6. Short-Term Investments and Investments in Securities

(1) Marketable securities classified as other securities at March 31, 2016 and 2015 were as follows:

		Millions	s of yen			
		2016				
	Acquisition cost	Gross unrealized gain	Gross unrealized loss	Carrying value		
Equity securities	¥ 25,413	¥32,827	¥629	¥ 57,612		
Government bonds, municipal bonds, etc. Other	38,844 80,700	1,750 676	-	40,593 81,376		
	¥144,957	¥35,253	¥629	¥179,581		
		Millions	s of yen			
		20	15			
	Acquisition cost	Gross unrealized gain	Gross unrealized loss	Carrying value		
Equity securities	¥ 26,528	¥37,295	¥—	¥ 63,823		
Government bonds, municipal bonds, etc.	41,353	1,388	_	42,741		
Other	39,700	864	-	40,564		
	¥107,581	¥39,547	¥—	¥147,128		

		Thousands of U.S. dollars			
		2016			
	Acquisition cost	Gross unrealized gain	Gross unrealized loss	Carrying value	
Equity securities	\$ 225,653	\$291,485	\$5,585	\$ 511,561	
Government bonds, municipal bonds, etc.	344,912	15,539	_	360,442	
Other	716,569	6,002	_	722,571	
	\$1,287,134	\$313,026	\$5,585	\$1,594,574	

Because no quoted market price is available and it is extremely difficult to determine the fair value, unlisted stocks of ¥62,828 million (\$557,876 thousand) and ¥68,669 million at March 31, 2016 and 2015, respectively, are not included in the above table.

(2) Proceeds from sales of, and gross realized gain on, other securities for the years ended March 31, 2016 and 2015 are summarized as follows:



(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 ¥705 million (\$6,260 thousand) for the year ended March 31, 2016.

Information on loss on devaluation of investments in securities was omitted since there are no items to be disclosed for the year ended March 31, 2015.

#### 7. Inventories

Inventories at March 31, 2016 and 2015 were as follows:

	Millions of yen		Thousands of U.S. dollars
	2016	2015	2016
Merchandise	¥ 4,338	¥ 3,003	\$ 38,519
Finished goods	13,416	10,902	119,126
Semi-finished goods and work in process	12,348	16,825	109,643
Raw materials and supplies	12,081	13,752	107,272
	¥42,183	¥44,482	\$374,560

Cost of sales included loss on devaluation of inventories of ¥1,185 million (\$10,522 thousand) and ¥1,689 million for the years ended March 31, 2016 and 2015, respectively.

#### 8. Loss on Impairment of Marketing Rights

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 market rights as follows:

			Millions of yen	Thousands of U.S. dollars
Location	Description	Items	2016	2016
The United Kingdom	Marketing rights for a prescription drug	Marketing rights	¥2,379	\$21,124
The United States	Marketing rights for a prescription drug	Marketing rights	204	1,812
			¥2,583	\$22,936

Due to the termination of a development collaboration agreement between Shionogi Limited, which is a subsidiary in the United Kingdom, and Egalet Corporation, Shionogi Limited recognized a loss on impairment equal to the carrying value of the corresponding marketing rights related to the compound in development. In addition, Shionogi Inc. in the United States recognized a loss on impairment equal to the reduction in the carrying value to the net realizable value of the corresponding marketing rights for a product as a result of the sale of the rights.

#### 9. Pledged Assets

Assets pledged as collateral at March 31, 2016 were as follows:

		Thousands of
	Millions of yen	U.S. dollars
	2016	2016
Cash and cash equivalents	¥7	\$62

The corresponding liabilities secured by such collateral at March 31, 2016 were as follows:

		Thousands of
	Millions of yen	U.S. dollars
	2016	2016
Deposits received from employees		
(included in "other current liabilities")	¥7	\$62

#### 10. 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, 2016 under non-cancellable operating leases are summarized as follows:

	Millions of yen	Thousands of U.S. dollars
Year ending March 31,	2016	2016
2016	¥293	\$2,602
2017 and thereafter	520	4,617
	¥813	\$7,219

#### 11. Long-Term Debt and Lease Obligations

Long-term debt and lease obligations at March 31, 2016 and 2015 consisted of the following:

	Millions of yen		Thousands of U.S. dollars
	2016	2015	2016
Unsecured loans from banks and financial institutions due through 2019 with an average interest rate of 2.0%	¥10,000	¥10,039	\$ 88,793
Zero coupon convertible bonds due in 2019	20,074	20,094	178,246
Finance lease obligations (included in "other current liabilities" and "other long-term liabilities")	613	708	5,443
	30,687	30,841	272,482
Less current portion	(282)	(284)	(2,504)
	¥30,405	¥30,557	\$269,978

The aggregate annual maturities of long-term debt and lease obligations subsequent to March 31, 2016 are summarized as follows:

Year ending March 31,	Millions of yen	Thousands of U.S. dollars
2016	¥ 282	\$ 2,504
2017	274	2,433
2018	10,072	89,433
2019	20,045	177,988
2020	14	124
	¥30,687	\$272,482

### 12. 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, 2016 and 2015

The changes in retirement benefit obligations are outlined as follows:

	Millions of yen		Thousands of U.S. dollars
	2016	2015	2016
Retirement benefit obligations at beginning of the year, as originally reported	¥83,577	¥81,402	\$742,115
Cumulative effect of change in accounting policy	_	3,128	_
Retirement benefit obligations at beginning of the year, as adjusted	83,577	84,530	742,115
Service cost	2,062	2,097	18,309
Interest cost	693	712	6,153
Actuarial (gain) loss	(1,390)	1,775	(12,342)
Retirement benefits paid	(6,650)	(5,537)	(59,048)
Retirement benefit obligations at end of the year	¥78,292	¥83,577	\$695,187

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

	Millions of yen		Thousands of U.S. dollars
	2016	2015	2016
Plan assets at fair value at beginning of the year	¥92,115	¥90,482	\$817,927
Expected return on plan assets	2,579	2,534	22,900
Actuarial (loss) gain	(2,648)	1,899	(23,513)
Contributions paid by the Group	1,487	1,869	13,204
Retirement benefits paid	(5,025)	(4,669)	(44,619)
Plan assets at fair value at end of the year	¥88,508	¥92,115	\$785,899

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
	2016	2015	2016
Funded retirement benefit obligations	¥ 76,072	¥ 81,267	\$ 675,475
Plan assets at fair value	(88,508)	(92,115)	(785,899)
	(12,436)	(10,848)	(110,424)
Unfunded retirement benefit obligation	2,220	2,309	19,712
Net asset for retirement benefits in consolidated balance sheet	(10,216)	(8,539)	(90,712)
Liability for retirement benefits	9,448	9,901	83,893
Asset for retirement benefits	(19,664)	(18,440)	(174,605)
Net asset for retirement benefits in consolidated balance sheet	¥(10,216)	¥ (8,539)	\$ (90,712)

The components of retirement benefit expenses for the years ended March 31, 2016 and 2015 are outlined as follows:

	Millions	Thousands of U.S. dollars	
	2016	2015	2016
Service cost	¥ 2,062	¥ 2,097	\$ 18,309
Interest cost	693	712	6,153
Expected return on plan assets	(2,579)	(2,534)	(22,900)
Amortization:			
Actuarial loss	1,418	2,186	12,591
Prior service cost	(204)	(204)	(1,811)
Retirement benefit expenses	¥ 1,390	¥ 2,257	\$ 12,342

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	
	2016	2015	2016	
Prior service cost	¥(204)	¥ (204)	\$(1,812)	
Actuarial loss	160	2,310	1,421	
Total	¥ (44)	¥2,106	\$ (391)	

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
	2016	2015	2016
Unrecognized prior service cost	¥(1,635)	¥(1,839)	\$(14,518)
Unrecognized actuarial loss	9,804	9,964	87,054
Total	¥ 8,169	¥ 8,125	\$ 72,536

The percentage composition of each major category of plan assets at fair value at March 31, 2016 and 2015 was as follows:

Asset class	2016	2015
Equity securities	37%	39%
General accounts controlled by life insurance companies	25	27
Debt securities	16	18
Other	22	16
Total	100%	100%

Total plan assets as of March 31, 2016 and 2015 include 30% and 29% of retirement benefit trusts established for corporate pension plans, respectively.

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, 2016 and 2015 are as follows:

	2016	2015
Discount rate	0.8%	0.8%
Expected long-term rate of return on plan assets (Weighted average)	2.8%	2.8%
Expected rate of salary increase (Weighted average)	3.4%	3.4%

#### (3) Defined contribution plans for the years ended March 31, 2016 and 2015

The total contributions paid by the Group to the defined contribution plans were ¥1,879 million (\$16,684 thousand) and ¥1,854 million for the years ended March 31, 2016 and 2015, respectively.

#### 13. 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 33.0% and 35.6% for the years ended March 31, 2016 and 2015, 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, 2016 and 2015 differ from the above statutory tax rates for the following reasons:

	2016	2015
Statutory tax rates	33.0%	35.6%
Expenses not deductible for income tax purposes	0.3	0.3
Dividends not taxable for income tax purposes	(2.2)	(6.1)
Amortization of goodwill	1.3	1.3
Tax credits	(5.7)	(6.0)
Inhabitants' per capita taxes	0.1	0.1
Difference in statutory tax rates of overseas subsidiaries	(1.3)	(2.8)
Decrease in deferred tax assets due to change in statutory tax rates	0.0	0.1
Increase in valuation allowance	6.9	9.6
Income taxes for prior period	_	14.7
Other	(0.8)	(0.7)
Effective tax rates	31.6%	46.1%

The tax effects of temporary differences at March 31, 2016 and 2015 which gave rise to significant deferred tax assets and liabilities are presented below:

	Millions of yen		Thousands of U.S. dollars
	2016	2015	2016
Deferred tax assets:			
Tax loss carry forwards	¥ 31,720	¥ 24,384	\$ 281,655
Research and development expenses	13,297	15,931	118,070
Adjustments to the carrying value of investments in a subsidiary	12,462	13,114	110,655
Accrued expenses and other current liabilities	2,330	3,767	20,689
Loss on revaluation of investments in securities	2,521	2,568	22,385
Provision for employees' bonuses	3,104	2,722	27,562
Provision for sales returns	920	1,098	8,169
Accrued enterprise taxes	1,460	1,240	12,964
Other	8,222	7,074	73,006
Valuation allowance	(50,916)	(43,710)	(452,104)
Total deferred tax assets	25,120	28,188	223,051
Deferred tax liabilities:			
Unrealized gain on other			
securities	(8,505)	(10,872)	(75,519)
Asset for retirement benefits	(2,905)	(2,517)	(25,795)
Investments in securities	(1,283)	(1,350)	(11,392)
Reserve for advanced depreciation of property,			
plant and equipment	(2,469)	(2,630)	(21,923)
Other	(4,349)	(4,669)	(38,618)
Total deferred tax liabilities	(19,511)	(22,038)	(173,247)
Net deferred tax assets	¥ 5,609	¥ 6,150	\$ 49,804

The "Act for Partial Amendment of the Income Tax Act, etc." (Act No.15 of 2016) and the "Act for Partial Amendment of the Local Tax Act, etc." (Act No.13 of 2016) were promulgated on March 29, 2016 and the corporation tax rate will be reduced from fiscal years beginning on or after April 1, 2016. Accordingly, the statutory tax rate used for calculating deferred tax assets and liabilities will be reduced from 32.2% to 30.8% for the temporary differences expected to be realized or settled during the period between April 1, 2016 and March 31, 2018 and to 30.6% for the temporary differences expected to be realized or settled from April 1, 2018.

As a result of this change in tax rates, deferred tax assets, net of deferred tax liabilities, income taxes-deferred and net unrealized holding gain on securities increased by ¥283 million (\$2,513 thousand), ¥31 million (\$275 thousand) and ¥445 million (\$3,951 thousand), respectively, and retirement benefit liability adjustments decreased by ¥131 million (\$1,163 thousand) as of and for the year ended March 31, 2016.

#### 14. Financial Instruments

#### (1) Overview

#### (a) Policies for financial instruments

The Company 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 four years, at the longest, subsequent to March 31, 2016.

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.

#### (e) Concentration of credit risk

At March 31, 2016 and 2015, 56% and 59%, respectively, of outstanding trade receivables represented receivables due from a specific and large-scale customer.

#### (2) Fair value of financial instruments

Carrying values of financial instruments on the consolidated balance sheets as of March 31, 2016 and 2015, their fair values and their differences 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.

	Millions of yen			
		2016		
	Carrying value	Fair value	Difference	
Cash and cash equivalents	¥127,744	¥127,744	¥ —	
Notes and accounts receivable – trade and affiliates	65,208	65,208	_	
Short-term investments and investments in securities	132,068	132,068	_	
Total assets	¥325,020	¥325,020	¥ —	
Notes and accounts payable – trade and affiliates	¥ 11,050	¥ 11,050	¥ —	
Accrued income taxes	19,397	19,397	-	
Long-term debt:				
Bonds	20,074	27,260	7,186	
Long-term loans	10,000	10,405	405	
Total liabilities	¥ 60,521	¥ 68,112	¥7,591	
Derivative transactions (*)	(26)	(26)	_	

\*Assets and liabilities arising from derivative transactions are shown at net value with the amount in parentheses representing net liability position.

	Millions of yen			
	2015			
	Carrying value	Fair value	Differ	rence
Cash and cash equivalents	¥ 78,722	¥ 78,722	¥	_
Notes and accounts receivable – trade and affiliates	70,585	70,585		_
Short-term investments and investments in securities	119,190	119,190		_
Total assets	¥268,497	¥268,497	¥	-
Notes and accounts payable – trade and affiliates	¥ 11,574	¥ 11,574	¥	_
Current portion of long-term debt:				
Current portion of long-term loans	39	39		_
Accrued income taxes	16,169	16,169		_
Long-term debt:				
Bonds	20,094	23,400	3,3	306
Long-term loans	10,000	10,399	3	399
Total liabilities	¥ 57,876	¥ 61,581	¥3,7	705

	Thousands of U.S. dollars			
	2016			
	Carrying value	Fair value	Difference	
Cash and cash equivalents	\$1,134,292	\$1,134,292	\$ —	
Notes and accounts receivable – trade and affiliates	579,010	579,010	_	
Short-term investments and investments in securities	1,172,687	1,172,687	_	
Total assets	\$2,885,989	\$2,885,989	\$ -	
Notes and accounts payable – trade and affiliates	\$ 98,117	\$ 98,117	\$ -	
Accrued income taxes	172,234	172,234	_	
Long-term debt:				
Bonds	178,245	242,053	63,808	
Long-term loans	88,794	92,390	3,596	
Total liabilities	\$ 537,390	\$ 604,794	\$67,404	
Derivative transactions (*)	(231)	(231)	_	

(a) Methods to determine the fair value of financial instruments, short-term investments and investments in securities

#### 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 6 "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.

#### • Bonds

The fair value of bonds is determined by quoted price offered by financial institutions.

#### • Long-term loans

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 15 "Derivative Transactions" of these notes to the consolidated financial statements.

(b) Financial instruments for which it is extremely difficult to determine the fair value

	Millions	Thousands of U.S. dollars	
	2016	2015	2016
Unlisted equity securities	¥62,828	¥69,912	\$557,876

Because no quoted market price is available and it is extremely difficult to determine the fair value, these financial instruments are not included in the above table.

# (c) The redemption schedule for monetary assets and marketable securities with maturities at March 31, 2016 and 2015

	Millions of yen					
	2016					
	Due in 1 year or less	Due afterDue after1 year5 yearsthroughthrough5 years10 years		Due after 10 years		
Cash and cash equivalents	¥127,738	¥ —	¥ —	¥ —		
Notes and accounts receivable – trade and affiliates	65,208	_	_	_		
Short-term investments and investments in securities:						
Government bonds, municipal bonds, etc.	_	_	14,000	2,000		
Other securities with maturities	49,687	1,514	_	_		
Total	¥242,633	¥1,514	¥14,000	¥2,000		

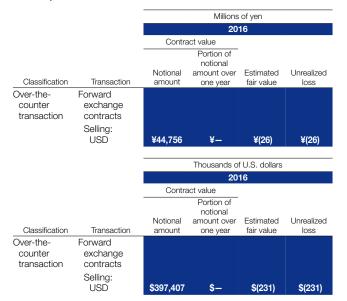
	Millions of yen					
	2015					
	Due after Due after					
	Due in	1 year	5 years			
	1 year	through	through	Due after		
	or less	5 years	10 years	10 years		
Cash and cash equivalents	¥ 78,715	¥ —	¥ —	¥ —		
Notes and accounts receivable – trade and affiliates	70,585	_	_	_		
Short-term investments and investments in securities:						
Government bonds, municipal bonds, etc.	_	_	14,000	2,000		
Other securities with maturities	30,762	1,581	-	-		
Total	¥180,062	¥1,581	¥14,000	¥2,000		

	Thousands of U.S. dollar					
	2016					
	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	\$1,134,239	\$ -	\$ -	\$ -		
Notes and accounts receivable – trade and affiliates	579,009	_	_	_		
Short-term investments and investments in securities:						
Government bonds, municipal bonds, etc.	_	_	124,312	17,759		
Other securities with maturities	441,192	13,443	_	_		
Total	\$2,154,440	\$13,443	\$124,312	\$17,759		

#### 15. Derivative Transactions

The information on derivative transactions for which hedge accounting does not apply for the year ended March 31, 2016 is as follows:

Currency-related transactions



There are no items to be disclosed for the year ended March 31, 2015.

#### 16. Contingent Liabilities

The Company was contingently liable for the guarantee of employees' housing loans of ¥5 million (\$44 thousand) at March 31, 2016.

#### 17. 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, 2016 and 2015 amounted to ¥5,388 million (\$47,842 thousand).

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.

In accordance with the Act, 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. Stock option expenses of ¥93 million (\$826 thousand) were included in selling, general and administrative expenses for the year ended March 31, 2016.

In accordance with the Act, 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. Stock option expenses of ¥80 million were included in selling, general and administrative expenses for the year ended March 31, 2015.

In accordance with the Act, 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.

In accordance with the Act, 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.

In accordance with the Act, 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 and 2015 plans of the Company during the year ended March 31, 2016 is summarized as follows:

	2015 plan	2014 plan	2013 plan	2012 plan	2011 plan
	Number of options				
Outstanding as of April 1, 2015	_	42,400	39,900	71,200	42,200
Vested	21,100	-	-	-	-
Exercised	-	2,000	2,000	3,800	2,600
Forfeited	_	-	-	-	-
Outstanding as of March 31, 2016	21,100	40,400	37,900	67,400	39,600

The unit price of the stock options after vesting under the 2011, 2012, 2013, 2014 and 2015 plans of the Company as of March 31, 2016 is summarized as follows:

		2015	plan	2014 plan		2013 plan			
			U.S.			U.S.			U.S.
	Ye	n	dollars	Ye	en	dollars	Ye	n	dollars
Unit price of stock options:									
Exercise price as of March 31, 2016	¥	1	\$ 0.01	¥	1	\$ 0.01	¥	1	\$ 0.01
Average market price per share upon exercise		_	_	4,	025	35.74	4,0	)25	35.74
Estimated fair value of unit price at grant date	4,	553	40.43	1,	899	16.86	1,9	930	17.14
		2012	plan		2011	plan			
	Ye	n	U.S. dollars	Ye	en	U.S. dollars			
Unit price of stock options:									
Exercise price as of March 31, 2016	¥	1	\$ 0.01	¥	1	\$ 0.01			
Average market price per share upon exercise	4,0	025	35.74	4,	025	35.74			
Estimated fair value of unit price at grant date	ę	916	8.13	1,	129	10.02			

Valuation method for estimating fair value was the Black-Scholes model. The major assumptions used for the 2015 plan were as follows:

Major assumptions	Note	2015 plan
Estimated volatility	(a)	27.14%
Estimated remaining period	(b)	5.3 years
Estimated dividend	(c)	¥52 per share
Risk-free rate	(d)	0.104%

(a) Estimated volatility was computed by the actual stock price of the Company during the period from March 2010 to July 2015.

[b)Estimated remaining period was the average period of stock option holders until retirement in accordance with internal regulations.

(c) The estimated dividend was calculated at the actual amount for the year ended March 31, 2015.

(d) The risk-free rate was based on the average rate of compound interest yield bonds, for which redemption dates were within three months of the estimated remaining period, in the statistics data for long-term interest-bearing government bonds published by the Japan Securities Dealers Association.

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.

Movements in issued shares of common stock and treasury stock during the years ended March 31, 2016 and 2015 are summarized as follows:

Number of shares						
	20	)16				
April 1, 2015	Increase	Decrease	March 31, 2016			
351,136,165	_	_	351,136,165			
25,564,239	5,183	10,400	25,559,022			
	Number	of shares				
-	20	15				
April 1, 2014	Increase	Decrease	March 31, 2015			
351,136,165	_	_ 14,700	351,136,165 25,564,239			
	2015 351,136,165 25,564,239 25,564,239 April 1, 2014 351,136,165	20 April 1, 2015 Increase 351,136,165 – 25,564,239 5,183 Number 20 April 1, 2014 Increase	2016           April 1, 2015         Increase         Decrease           351,136,165         -         -           25,564,239         5,183         10,400           Number of shares           2015           April 1, 2014         Increase         Decrease           351,136,165         -         -         -			

The increase in the number of shares of treasury stock during the year ended March 31, 2016 is 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, 2016 is due to the exercise of share subscription rights.

The increase in the number of shares of treasury stock during the year ended March 31, 2015 consists of 9,329,900 shares due to the purchase of shares based on the resolution of the Board of Directors and 6,338 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, 2015 is due to the exercise of share subscription rights.

#### 18. Supplementary Information on Consolidated Statement of Income

#### Reversal of provision for sales returns

Reversal of provision for sales returns included in net sales and cost of sales for the years ended March 31, 2016 and 2015 amounted to ¥459 million (\$4,076 thousand) and ¥1,447 million, respectively.

#### Research and development expenses

Research and development expenses included in selling, general and administrative expenses for the years ended March 31, 2016 and 2015 amounted to ¥49,788 million (\$442,088 thousand) and ¥48,870 million, respectively.

#### Gain on business transfer

Gain on business transfer for the year ended March 31, 2015 represents the transfer of all assets of the Company's wholly-owned subsidiary providing glycan analytical services in the United States.

#### Litigation settlement

Litigation settlement for the years ended March 31, 2016 and 2015 represents the settlement that was reached between the Company and Eli Lilly Japan K.K., and the settlement that was reached between Shionogi Inc., and Cowen Healthcare Royalty Partners, respectively.

#### Special retirement expenses

Special retirement expenses for the years ended March 31, 2016 and 2015 are retirement expenses incurred by the Company and Shionogi Inc., and retirement expenses incurred by Shionogi Inc., respectively.

#### 19. Other Comprehensive Income

The following table presents the analysis of other comprehensive (loss) income for the years ended March 31, 2016 and 2015.

	Millions	Thousands of U.S. dollars	
	2016	2015	2016
Net unrealized holding (loss) gain on securities:			
Amount arising during the year	¥ (1,929)	¥ 4,018	\$ (17,129)
Reclassification adjustments included in profit or loss	(2,362)	(67)	(20,973)
Before tax effect	(4,291)	3,951	(38,102)
Tax effect	2,364	(566)	20,991
Total	(1,927)	3,385	(17,111)
Deferred loss on hedges:			
Amount arising during the year	(249)	(416)	(2,211)
Reclassification adjustments included in profit or loss	249	416	2,211
Before tax effect	-		-
Tax effect	_	_	_
Total	_	-	—
Translation adjustments:			
Amount arising during the year	(11,385)	10,426	(101,092)
Reclassification adjustments			
included in profit or loss	-	(18)	
Before tax effect	(11,385)	10,408	(101,092)
Tax effect			
Total	(11,385)	10,408	(101,092)
Retirement benefit liability adjustments:			
Amount arising during the year	(1,259)	124	(11,179)
Reclassification adjustments included in profit or loss	1,215	1.982	10,788
Before tax effect	(44)	2,106	(391)
Tax effect	(117)	(1,026)	(1,039)
Total	(161)	1,080	(1,430)
Other comprehensive (loss) income	¥(13,473)	¥14,873	\$(119,633)

#### 20. Related Party Transactions

Related party transactions for the years ended March 31, 2016 and 2015 and the related balances at March 31, 2016 and 2015 are summarized as follows:

# (1) Principal transactions between the Company and a related party

	Millions of yen
	2015
Shunjusha Co., Ltd.:	
Rent expense — building	¥19
Lease deposits, a component	
of other assets	4

There are no items to be disclosed for the year ended March 31, 2016.

# (2) Principal transactions between a consolidated subsidiary and a related party

	Millions	Thousands of U.S. dollars	
	2016	2015	2016
Shunjusha Co., Ltd.:			
Rent received — land and office building	¥ 50	¥ 50	\$ 444
Rent expense — building	166	147	1,474
Management fee for leased property	4	4	36
Lease deposits, a component of other assets	46	42	408
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 percentages of voting rights owned by these two people were 100% as of March 31, 2016 and 2015. Shunjusha Co., Ltd. is located in Chuo-ku, Osaka with a capital amount of ¥100 million (\$888 thousand) at March 31, 2016 and 2015.

The prices for the above related party transactions were determined with reference to market value, transactions made in the same area and so on.

#### 21. Amounts per Share

Amounts per share as of and for the years ended March 31, 2016 and 2015 were as follows:

	Ye	U.S. dollars	
	2016	2015	2016
Profit	¥ 204.83	¥ 132.67	\$ 1.82
Diluted profit	201.70	132.04	1.79
Net assets	1,564.73	1,456.70	13.89
Cash dividends applicable to the year	62.00	52.00	0.55

Profit per share is computed based on the profit attributable to shareholders of common stock and the weighted-average number of shares of common stock outstanding during the year. Diluted profit per share is computed based on the profit attributable to shareholders of common stock and the weighted-average number of common shares outstanding during the year after giving effect to the dilutive potential of shares of common stock to be issued upon the exercise of stock options. Net assets per share have been computed based on 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, 2016 and 2015 in the table above is summarized as follows:

	Millions	Thousands of U.S. dollars	
	2016	2015	2016
Profit attributable to owners of parent	¥66,687	¥44,060	\$592,142
Adjustments to profit attributable to owners of parent:			
Interest income, net of tax	(13)	(4)	(115)

	Thousands of shares		
	2016	2015	
Weighted-average number of shares of common stock outstanding	325,578	332,103	
Increase in common stock:			
Bonds	4,788	1,376	
Share subscription rights	200	184	
Total	4,988	1,560	

The financial data used in the computation of net assets per share at March 31, 2016 and 2015 in the above table is summarized as follows:

	Millions of yen		Thousands of U.S. dollars
	2016	2015	2016
Total net assets	¥513,877	¥478,883	\$4,562,928
Amounts deducted from total net assets:			
Amounts attributable to share subscription rights in total net assets	(352)	(270)	(3,126)
Amounts attributable to non-controlling interests in total net assets	(4,086)	(4,354)	(36,281)
Net assets used in the computa- tion of net assets per share	¥509,439	¥474,259	\$4,523,521
Thousands of shares			
	2016	2015	
Number of shares used in the computation of net assets per share	325,577	325,571	

#### 22. Segment Information

# 1. Segment information for the years ended March 31, 2016 and 2015

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 Groupwide basis. Therefore, disclosure of segment information for the years ended March 31, 2016 and 2015 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, 2016 and 2015, information on sales by product and service was omitted.

#### (2) Geographical information

(a) Net sales

	Millions of yen		Thousands of U.S. dollars
	2016	2015	2016
Japan	¥175,534	¥185,370	\$1,558,640
Europe	102,393	50,860	909,190
(United Kingdom)	(96,682)	(50,434)	(858,480)
North America	21,088	26,621	187,249
(United States of America)	(21,082)	(26,615)	(187,196)
Other	10,958	11,140	97,301
Total	¥309,973	¥273,991	\$2,752,380

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:

Europe: United Kingdom, Switzerland, Germany and others
 North America: United States of America and others
 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, 2016 and 2015, information on property, plant and equipment by geographical segment was omitted.

#### (3) Information by major customer

	Net sales			
	Millions	s of yen	Thousands of U.S. dollars	Related
Customer name	2016	2015	2016	segment name
SUZUKEN CO., LTD.	¥60,351	¥66,720	\$535,882	Pharmaceuticals
AstraZeneca UK Limited	¥47,850	¥47,829	\$424,880	Pharmaceuticals
Viiv Healthcare UK Limited	¥40,474	¥ 5,832	\$359,386	Pharmaceuticals
TOHO PHARMACEUTICAL CO., LTD.	¥31,796	¥34,914	\$282,330	Pharmaceuticals

#### 3. Information on loss on impairment of property, plant and equipment 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 at March 31, 2016 and 2015, and for the years then ended 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, 2016 and 2015 and for the years then ended was omitted.

# 5. Information on the remaining balance and gain on negative goodwill by reportable segment

Information on the remaining balance and gain on negative goodwill was omitted since there are no items to be disclosed at March 31, 2016 and 2015 and for the years then ended.

#### 23. Subsequent Event

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, 2016, was approved at a shareholders' meeting held on June 23, 2016:

	Millions of yen	Thousands of U.S. dollars
Cash dividends (¥34.00 = U.S.\$0.30 per share)	¥11,070	\$98,295

# **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, 2016, 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, 2016, 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 5.

Ernst & Young Shin Nihon LLC

June 22, 2016 Osaka, Japan

### Corporate Information (As of March 31, 2016)

#### 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: 5,896

Fiscal Year-End March 31

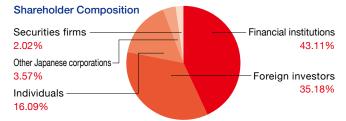
Website http://www.shionogi.co.jp/en/

#### Investor information

Stock (Securities) Listings Tokyo (#4507)

(Shares listed in 1949) Common Stock Authorized: 1,000,000,000 shares Issued: 351,136,165 shares

Number of shareholders: 31,628



Note: Calculated Individuals including treasury stock

#### Major Shareholders

Name	Number of shares (Thousands)	Percentage of total shares
The Master Trust Bank of Japan, Ltd. (as a trustee)	29,391	9.02
Japan Trustee Services Bank, Ltd. (as a trustee)	25,264	7.75
Sumitomo Life Insurance Company	18,604	5.71
JP MORGAN CHASE BANK 385147	16,638	5.11
Japan Trustee Services Bank, Ltd. (as a trustee for (i) Sumitomo Mitsui Trust Bank Ltd. and (ii) retirement benefit		
of Sumitomo Mitsui Banking Corporation)	9,485	2.91
Nippon Life Insurance Company	8,409	2.58
Sumitomo Mitsui Banking Corporation	6,564	2.01
STATE STREET BANK WEST CLIENT - TREATY 505234	5,021	1.54
SUZUKEN CO., LTD.	4,341	1.33
Trust & Custody Services Bank, Ltd. (as a trustee)	4,276	1.31

Notes:

1. The Company holds 25,559,022 shares of treasury stock. However, this shareholding is not included in the list of top-10 shareholders.

 The percentage of total shares is calculated as a proportion of 325,577,143 shares, which is the total number of issued shares less treasury stock of 25,559,022 shares.

#### Major Business Locations / Major Consolidated Subsidiaries

#### Head Office / Branch Offices

#### Head Office

1-8, Doshomachi 3-chome, Chuo-ku, Osaka 541-0045, Japan Tel: +81-6-6202-2161 Fax: +81-6-6229-9596

#### Tokyo Branch Office

7F, Tekko Building, 1-8-2, Marunouchi, Chiyoda-ku, Tokyo 100-0005, Japan TEL +81-3-5219-7310

#### Offices

Global Development Office 12F, Hankyu Terminal Bldg., 1-4, Shibata 1-chome, Kita-ku, Osaka 530-0012, Japan Tel: +81-6-6485-5055

Human Health Care Division Office 8F, Nissay Yodoyabashi East, 3-13, Imabashi 3-chome, Chuo-ku, Osaka 541-0042, Japan Laboratories

#### Shionogi Pharmaceutical Research Center 1-1, Futaba-cho 3-chome, Toyonaka, Osaka 561-0825, Japan Tel: +81-6-6331-8081

Shionogi Innovation Center for Drug Discovery Kita 21, Nishi 11, Kita-ku, Sapporo, Hokkaido 001-0021, Japan Tel: +81-11-700-4700

Plants

Settsu Plant 5-1, Mishima 2-chome, Settsu, Osaka 566-0022, Japan Tel: +81-6-6381-7341

#### Kanegasaki Plant

7, Moriyama, Nishine, Kanegasaki-cho, Isawa-gun, Iwate 029-4503, Japan Tel: +81-197-44-5121

Administration Offices

Kuise Site

1-3, Kuise Terajima 2-chome, Amagasaki, Hyogo 660-0813, Japan Tel: +81-6-6401-1221

#### Aburahi Facilities

1405, Gotanda, Koka-cho, Koka, Shiga 520-3423, Japan Tel: +81-748-88-3281

#### Overseas Offices (Outside Japan)

Shionogi & Co., Ltd. Taipei Office 4F, No. 2, Sec. 2, Nanking East Road, Taipei 10457, Taiwan Tel: +886-2-2551-6336

#### Shionogi & Co., Ltd. Shanghai Office

Room 1589, 15/F L'Avenue, Shanghai, 99 Xian Xia Rd., Chang Ning, Shanghai, China 200051 Tel: +86-21-6057-7089

Major Consolidated Subsidiaries (Year established) Shionogi Healthcare Co., Ltd. (2016) 7F, Yodoyabashi Square, 6-18, Kitahama 2-chome, Chuo-ku, Osaka 541-0041, Japan Tel: +81-6-6202-2728 Shionogi Pharma Chemicals Co., Ltd. (1976) 224-20, Ebisuno Hiraishi, Kawauchi-cho, Tokushima 771-0132, Japan Tel: +81-88-665-2312 Shionogi Analysis Center Co., Ltd. (2007) 5-1, Mishima 2-chome, Settsu, Osaka 566-0022, Japan Tel: +81-6-6381-7271 Saishin Igaku Co., Ltd. (1998) Shionogi Doshomachi Bldg 7F, 7-6, Doshomachi 4-chome, Chuo-ku, Osaka 541-0045, Japan Tel: +81-6-6222-2876 Shionogi Techno Advance Research Co., Ltd. (2010) 3-1-1, Futaba-cho, Toyonaka, Osaka 561-0825, Japan Tel: +81-6-6331-8605 Shionogi General Service Co., Ltd. (1992) 7-6, Doshomachi 4-chome, Chuo-ku, Osaka 541-0045, Japan Tel: +81-6-6227-0815 Taiwan Shionogi & Co., Ltd. (1963) 4F, No. 2, Sec. 2, Nanking East Road, Taipei 10457, Taiwan Tel: +886-2-2551-6336 Shionogi Inc. (2008) 300 Campus Drive, Florham Park, NJ 07932, USA Tel: +1-973-966-6900 C&O Pharmaceutical Technology (Holdings) Ltd. (2003) 911-12, Silvercord Tower 2, 30 Canton Road, Tsim Sha Tsui, Kowloon, Hong Kong Tel: +852-2806-0109 Shionogi Limited (2012) 33 Kingsway, London WC2B 6UF, United Kingdom Tel: +44-20-3053-4200 Beijing Shionogi Pharmaceutical Technology Limited (2013) Room 07, 20th Floor, Jinghui Building, No. 118, Jianguo Road B, Chaoyang District, Beijing 100022 Tel: +86-10-6567-8002

Hei +86-10-0507-8002
 Shionogi Singapore Pte. Ltd. (2013)
 10 Anson Rd., #34-14 International Plaza, Singapore 079903
 Tel: +65-62231617

(As of June 30, 2016)



# 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.



Shionogi's Action Guidelines

# Vision

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

# **Values**

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







