

Message from the President

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



Progress with the SGS2020 Medium-Term Business Plan

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

During SGS2020, global sales of *Tivicay*, *Triumeq* and *Juluca*, which are all based on our anti-HIV agent dolutegravir, have

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

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

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

Net sales

¥363.7 billion

(YoY +5.5%)

Increased for 4 consecutive years

Operating income

¥138.5 billion

(YoY +20.2%)

Higher than the levels achieved in prior fiscal years for 4 consecutive years

Ordinary income

¥166.6 billion

(YoY +20.1%)

Higher than the levels achieved in prior fiscal years for 7 consecutive years

Profit attributable to owners of parent

¥132.8 billion

(YoY +21.9%)

Higher than the levels achieved in prior fiscal years for 3 consecutive years

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

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

Continuing to focus on the three key points that define Shionogi

(1) Drive innovation primarily through R&D


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

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

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

(2) Balance the needs of four stakeholder groups

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

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

(3) Pursue efficiency

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

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

Tackling three key issues to deliver growth over the longer term

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

Three key issues to deliver longer-term growth

Issue 1
Discover and develop next-generation growth drivers to take over from dolutegravir
Issue 2
Reinforce the domestic business and establish a global presence
Issue 3
Create new value and reinforce the business base


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

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

I have already highlighted Shionogi’s powerful R&D capabilities, which are anchored by a strong commitment to innovation. We have made particularly good progress in recent years thanks to improvements to our drug development infrastructure overseas and a growing track record built up through the global development of proprietary drugs such as *Xofluza*, one of our new family of small-molecule drugs. However, there are still many

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

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

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

Issue 2 Reinforce the domestic business and establish a global presence

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

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

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

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

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

Targeting sustained growth after 2020

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

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

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

Issue 3 Create new value and reinforce the business base

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

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

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

Cultivating people to support Shionogi's sustained growth


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

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

The President's Management Seminar, which I have held for seven years, starting in 2012, is another way we are working to train future leaders. My seminar, and the Management Seminars run by division heads, are used to foster the next-generation of business leaders and senior managers from the current manager cohort. To ensure that our senior managers have a full

and detailed understanding of the Group's operations, executive officers have to work as general managers at a minimum of two divisions, including a division where they have no previous experience, while candidates for senior managerial positions are required to have management experience as the president of a Group company and as a non-executive director or auditor at a Group company. These various initiatives are designed to promote and sustain diversity.


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

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

ESG initiatives

The Sustainable Development Goals (SDGs) adopted by the United Nations in 2015 and other trends are spurring growing interest in environment, social and governance (ESG) issues worldwide, which is putting more pressure on companies to play a greater role in realizing sustainable societies. As mentioned earlier, we face climate change, a rising global population and aging societies in upper middle income countries. Shionogi needs to address those accelerating environmental and social changes in order to grow sustainably by contributing to a more vigorous society through improved healthcare. We have identified the material issues that matter most to Shionogi (materiality) and disclosed them to

stakeholders. The social issues that we strive to address, and driving innovation to help solve those issues, define our priorities, and we have accordingly highlighted a number of key ESG issues that Shionogi needs to tackle as a public entity. As with our efforts in personnel development, senior managers have to do their part to further strengthen our corporate culture, characterized by the phrase, "automatically thinking and doing the right thing at all times."

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

Governance and compliance

Reinforcing governance and ensuring compliance are vital to sustaining our business activities in the long term. Shionogi has already taken numerous steps to improve corporate governance. We have put in place systems and set out rules to ensure rapid, bold decision-making processes that are transparent and fair from the perspective of all our stakeholders – from patients and medical professionals to shareholders and investors, communities and employees. Aiming to achieve the highest levels of governance, Shionogi was also one of the first companies in Japan to appoint outside directors in 2009, the year after I became President, and we have worked to create a

more diverse board of directors, including the appointment of the first female director from within the company in 2015. With compliance, we strive to ensure our staff comply with social norms and behave in an ethical manner as both employees and members of society, in addition to strict compliance with laws, rules and regulations.


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

Sharing the benefits of growth with shareholders

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

For fiscal 2018, we paid an annual dividend of ¥94 per share, an increase of ¥12 from the previous fiscal year. We have now raised the dividend for seven consecutive years. Following on from fiscal 2017, we also repurchased and cancelled approximately 7.35 million shares of common stock, accounting for 2.3% of total issued shares before

cancellation. In recent years, we have held treasury stock equivalent to around 3% of total issued shares, but after a review aimed at enhancing the flexible use of capital resources, we reduced our holding to 1.8% through cancellation. We plan to maintain the ratio at around 2%, aiming to increase corporate value while flexibly deploying capital. Going forward, we will continue to use our shareholder return policy to pass on the benefits of Shionogi's growth to shareholders.

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



A final word

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

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